

**UNITED STATES AIR FORCE
ARMSTRONG LABORATORY**

**Review of Ecological Risk Assessment
Guidelines**

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PREFACE

This document was produced under the auspices of the Environmental Risk Assessment Program (ERAP), which has its genesis in the DOD/DOE Strategic Environmental Research and Developmental Program (SERDP) that was established through Public Law 101-510 (10 United States Code 2901-2904). ERAP was established as a cooperative effort of DOD, DOE, and EPA to improve health and ecological risk assessments and to foster consistency in risk assessments across federal agencies. The program has three working groups chartered under its mission which are the Materials/Chemicals Risk Assessment (MCRA) Working Group, Human Risk Assessment Methodology (HRAM) Working Group, and the Ecological Risk Assessment Methodology (ERAM) Working Group. The program also has an Advisory and Coordinating Committee (ACC) that oversees the program and the working group's activities.

The focus of the Environmental Risk Assessment Methods (ERAM) Working Group is the review, evaluation and development of methodologies for assessing human and environmental risks related to federal facilities. The members of this Working Group include Dr Heino Beckert, chairperson (U.S. Department of Energy), Dr Chris Cubbison (U.S. Environmental Protection Agency), Dr Merrill Heit (U.S. Department of Energy), Dr Steven Hwang (U.S. Department of Energy), Lt Col Robert Kull (U.S. Air Force), Capt Kathleen MacMahon (U.S. Air Force), Dr Bruce Peirano, (U.S. Environmental Protection Agency), Dr Ron Porter (U.S. Air Force), CAPT Kenneth Still, (U.S. Navy), Dr Sylvia Talmage (Oak Ridge National Laboratory), Dr Robert Ross (Oak Ridge National Laboratory), Dr Po-Yung Lu (Oak Ridge National Laboratory), Dr Randy Wentsel (U.S. Army), and Dr Janet Whaley (U.S. Army). LTC Dan Caldwell (U.S. Army, retired) served as the ERAM chair and co-chairperson through April, 1995. This report was prepared by Dr. S. Talmage of Oak Ridge National Laboratory, and benefited from technical review by members of the working Group.

The ERAP Advisory and Coordinating Committee endorses the information contained within this document with the understanding that the end user is responsible for its application. This means that users are responsible for obtaining any internal scientific and policy reviews required prior to its acceptance within other organizations.

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1. INTRODUCTION

Currently there are no published regulatory methodologies for ecological risk assessment provided by federal or state agencies; however, general guidelines have been proposed by several agencies. As part of a cooperative effort of the Department of Defense (DOD), the Department of Energy (DOE), and the U.S. Environmental Protection Agency (EPA) to standardize ecological risk assessment across federal agencies, this report summarizes and reviews available information on guidelines used in the ecological risk assessment process. Currently available guidelines have been developed primarily by the U.S. EPA for Superfund sites. The publication of U.S. EPA guidance documents has been in response to SARA 110 and CERCLA 104(i) which emphasize the need for an assessment of the actual and potential risks to public health and the environment at National Priority List (NPL) sites. While these guidelines concentrate on Superfund sites and hazardous substances designated under CERCLA, they could be applied to other sites and other hazardous substances. Other federal agencies are in the process of developing guidelines for contaminants and sites under their jurisdiction.

The U.S. EPA has developed a detailed methodology for human health risk assessment; however, it is more difficult to develop a similar methodology for ecological risk assessments. The basic reason for this is that in comparison to human health assessments, where the individual is the endpoint or resource to be protected, the ecological resources to be protected are more difficult to define. Ecological resources range from the species and population level to the community and ecosystem level. In addition, there is no single set of ecological values to be protected; values are selected from a range of possibilities based on both scientific and policy considerations. Ecological risk assessment guidelines must have the flexibility to be applied to various sites having different ecosystem types, composed of different media, and containing correspondingly different animal and plant resources. Ecological risk assessments may involve multiple species that are exposed at different levels of contaminants and that may respond differently to the same contaminants. Ecosystems also contain abiotic as well as biotic components. In addition to risks from chemicals, ecological risk assessment is also concerned with physical changes to the environment such as habitat destruction which may occur during site remediation. For these reasons, procedures for ecological risk assessment have thus far been defined in only general terms and a certain amount of professional judgement must be used in conducting an ecological risk assessment at a particular site. Most guidelines stress an integrated approach involving measurement of chemical contamination, laboratory toxicity tests, field assessments, and models in assessing risk. At present, ecological risk assessments range in complexity from screening level assessments using available criteria and available site data to complex models supported by extensive field sampling data.

In general, the four elements of a human health risk assessment, **hazard identification**, **dose-response assessment**, **exposure assessment**, and **risk characterization** (NRC, 1983), are applicable to ecological risk assessments; however, as previously mentioned, the response of individual humans to a specific chemical or chemical mixture is the endpoint of concern in a human health risk assessment, whereas the ecosystem as represented by populations of plants and animals is the endpoint in an ecological risk assessment. Even so, effects on individual organisms may be used to predict effects at the population or higher levels and effects at the species level may be important in protecting endangered species. Dose-response characterization is based on laboratory and/or field bioassays; however, only representative species can be tested and the results may not be applicable to all indigenous species at a site. Ecological exposure assessments have the same limitations and often must be based on modeling studies. Currently, ecological risk assessments are performed primarily at sites that have been identified as hazardous (large, long-standing problems), i.e., CERCLA (Superfund) or RCRA sites. Thus, the assessment is motivated by the existence of the site, regardless of evidence of exposure or effects, and is part of the Remedial Investigation/Feasibility Study (RI/FS) which evaluates the site's potential impacts on public health, welfare, and the environment, and during which a cost-effective remedial action plan is developed.

2. ECOLOGICAL RISK ASSESSMENT GUIDANCE

2.1. CURRENT U.S. EPA GUIDANCE

A wide variety of approaches to ecological risk assessments are available; these range from screening level assessments using available criteria such as U.S. EPA Water Quality Criteria and available site data, to the use of complex models supported by extensive field sampling. Ecological risk assessments are generally site-specific, depending on the type of ecosystem(s) involved; the characteristics of natural resources at risk; the quality and quantity of available data; and the extent, degree, variation, and complexity of contamination. The publication of U.S. EPA guidance documents has been in response to SARA 110 and CERCLA 104(i) which emphasize the need for an assessment of the actual and potential risks to public health and the environment at NPL sites. None of the documents provide definitive methodologies at this time because the field of ecological risk assessment is relatively new, complex, and constantly evolving; more definitive methodologies are being developed. The U.S. EPA's Risk Assessment Forum is responsible for developing Agency-wide ecological risk assessment guidelines which is seen as a multiyear project.

The report, *Risk Assessment Guidance for Superfund, Volume II: Environmental Evaluation Manual, Interim Final* (U.S. EPA, 1989a), was developed for use during Removal

and RI/FS conducted at Superfund sites by Remedial Project Managers and On-Scene Coordinators (non-technical personnel) responsible for ensuring a thorough evaluation of actual or potential environmental effects. It presents an overall framework for considering environmental effects but does not provide detailed steps for conducting the evaluation. Instead, it discusses issues and provides a framework for designing studies that will evaluate effects of contaminants on sensitive species and the effects of remedial actions. It is assumed that Remedial Project Managers and On-Scene Coordinators will obtain assistance from technical specialists and ecologists. Specific field or laboratory methods that may be used in evaluating potential ecological effects are discussed in *Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document* (U.S. EPA, 1989b). The *Superfund Exposure Assessment Manual* (U.S. EPA, 1988a) describes methods for estimating and modeling the fate and transport of contaminants in the environment.

Supplemental Risk Assessment Guidance for the Superfund Program, Part 2 (U.S. EPA, 1989c) prepared by the U.S. EPA Region 1 Risk Assessment Work Group (1) addresses the collection of site-specific data needed to support ecological risk assessments, (2) describes a framework for conducting ecological risk assessments at Superfund sites, emphasizing the need for integration of information from laboratory tests, field assessments, and models in assessing risk, and (3) provides several specific approaches for assessing risk to ecosystems exposed to chemical contamination in different media. Data collection includes collection of all available background information, a site visit by a qualified field biologist, and development of a sampling plan. The sampling plan should address the following: the extent of contamination (chemicals present as well as distribution and concentrations), the fate and transport of contaminants, receptor organisms and habitats, and potential exposure pathways. The objectives of the sampling plan must be clearly stated. The first step of data collection includes chemical data, biological data, and physical characterization of the site. Contaminants may be selected based on persistence, high bioaccumulation potential, toxicity, or elevation above naturally occurring levels. Indicator species and possible endpoints may be selected based on importance to the ecological system, sensitivity, relevance to human beneficial uses, availability of practical methods for prediction and measurement, or trustee species or regulatory requirements.

In the second step in the ecological risk assessment process as described in U.S. EPA (1989c), information collected during the sampling process is used to conduct a screening level risk assessment. Thus, simple bioassays, available chemical analyses, simple models, and available toxicity criteria are used, along with worst case assumptions concerning exposure, to predict effects on receptors. The guidelines noted the lack of chronic criteria for screening purposes for terrestrial organisms. Based on the results of the screening level risk assessment, a more detailed assessment may be conducted. During this process both an exposure assessment and a toxicity assessment should be conducted. The exposure

assessment should address the following: what biological resources are exposed, what are the pathways/routes of exposure, and what is the magnitude, duration, and frequency of exposure. Thus the exposure assessment consists of source characterization, transport and fate analysis, exposure scenarios, and duration and frequency of exposure. In the absence of field data, chemical concentrations can be estimated using models. The toxicity assessment should characterize the chemicals of concern in terms of metabolism, adverse effects, and dose-response by receptor species and should take the chemical agent's fate in the environment into consideration.

The risk characterization should answer the questions: "what is the probability that adverse effects to the receptors of concern will result from the estimated exposure and what is the degree of confidence in the risk estimate?" Risk estimates may be expressed qualitatively or quantitatively depending on available data. The Quotient Method is the simplest method routinely used for quantitative risk (See Section 6).

The *Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document* (U.S. EPA, 1989b) provides guidance on designing, implementing, and interpreting ecological risk assessments at hazardous waste sites. It discusses ecological endpoints, assessment strategies, field sampling designs, quality assurance, data quality objectives, toxicity tests, biomarkers, field assessments, and data interpretation. The need for a combination of chemical, ecological, and toxicological data is stressed. Chemical analyses of appropriate media establish the presence, concentrations, and variabilities of specific toxic chemicals. Ecological surveys help to establish that adverse ecological effects have occurred. Toxicity tests establish a link between adverse effects and the concentration of the contaminants. This combination helps to rule out natural variability and physical habitat alterations as the cause of the effects. Overall, the document provides input into the decision-making process for site prioritization, waste characterization, site characterization, cleanup or remediation, and site monitoring, but does not provide definitive guidelines or methodologies. The importance of using site-specific endpoints and reasonably accurate indices of ecological effects is stressed.

Responding to the need for uniform guidelines in approaching ecological risk assessment, the EPA Risk Assessment Forum has published their *Framework for Ecological Risk Assessment* (U.S. EPA, 1992a) as a first step in their program to develop general risk assessment guidelines for hazardous waste sites. This report is an initial step in the U.S. EPA's long-term program to develop comprehensive risk assessment guidelines for ecological effects. It provides a basic framework for evaluating scientific information on the adverse effects of physical and chemical stressors on the environment, but does not provide specific guidance on use of data, models, endpoints, etc., necessary to conduct an ecological risk assessment. It fosters a consistent approach to ecological risk assessment within EPA,

identifies key issues, and defines terminology. The Risk Assessment Forum is currently working to create a general guidance document at a greater level of detail. This draft guidance document (U.S. EPA 1995a), available for comment, expands upon some framework concepts and modifies others to reflect U.S. EPA experience since publication of the framework.

The Framework (U.S. EPA 1992a), including the terminology used, has generally been accepted by the scientific community as the paradigm for ecological risk assessment. Ecological risk assessment is defined as a process that evaluates the likelihood that adverse ecological effects are occurring or may occur as a result of exposure to one or more stressors. The framework includes the following major phases (see Figure 2-1):

- (1) **problem formulation** (preliminary characterization of exposure and effects and examination of scientific data and data needs, policy and regulatory issues, and site-specific factors),
- (2) **analysis** (characterization of both exposure and ecological effects), and
- (3) **risk characterization** (evaluation of adverse ecological effects associated with exposure to a stressor).

Discussions between the risk assessor and risk manager result in decisions about **risk management**. It is assumed that limited site data will be available during the initial problem formulation. "The outcome of problem formulation is a conceptual model that describes how a given stressor might affect ecological components of the environment. The conceptual model also describes the relationship among assessment and measurement endpoints, the data required, and the methodologies that will be used to analyze the data." Depending on the available data, risk characterization may be qualitative or quantitative. Several workshops preceded this publication (U.S. EPA, 1992b, 1992c).

The Framework (U.S. EPA, 1992a) contains elements similar to the National Research Council's (1983) paradigm for human health risk assessment. Although problem formulation is not explicitly expressed in the NRC paradigm, planning issues are present at the start of all risk assessments. Thus, the Framework differs from the NRC paradigm in that problem formulation is added to the beginning of the process to determine the scope of the assessment. Hazard identification and dose-response assessment are combined in an ecological effects assessment phase, and the term stressor-response (to include physical changes such as habitat alteration) is used instead of dose-response. The exposure assessment and effects assessment are combined in an analysis phase as shown in Figure 2-1.

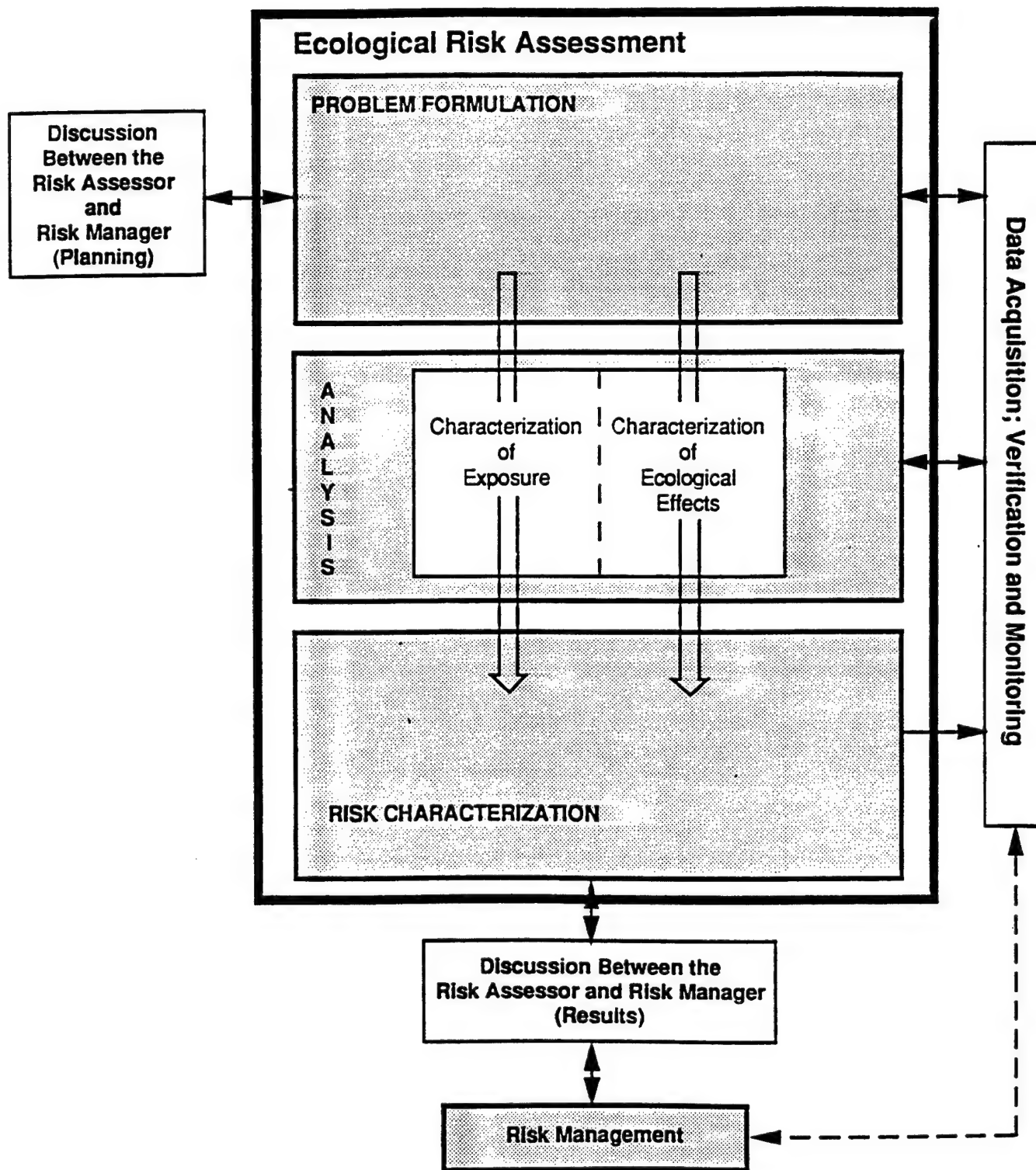


Figure 2-1. The U.S. EPA Framework for Ecological Risk Assessment
Source: U.S. EPA, 1992a

A draft report, *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (U.S. EPA, 1994a), describes a process for designing and conducting technically defensible ecological risk assessments within the Superfund program that is consistent with the EPA Framework. This document supersedes *Risk Assessment Guidance for Superfund, Volume II: Environmental Evaluation Manual* (U.S. EPA, 1989a) but does not repeat the statutory and regulatory requirements, basic ecological concepts, and other background information contained in the earlier document. A process is outlined that should result in a technically defensible, appropriately scaled, and site-specific ecological risk assessment. The document stresses decision points, primarily in the problem formulation stage.

As can be seen in the outline below, ecological risk assessment is a repetitive/iterative process with several steps occurring simultaneously and with a need for scientific expertise and professional judgment at many points. The procedure is aimed at site managers. The following are suggested steps in the baseline ecological risk assessment process at Superfund sites:

(1) Preliminary problem formulation and ecological effects evaluation

Site visit/description: environmental setting

Determine known or suspected contaminants

Use of highest (conservative) media concentrations

Probable contaminant fate and transport, including offsite migration

Chemical toxicity data; possible receptors

Complete exposure pathways

Evaluation of ecological effects

Compilation of chemical toxicity profiles

Development of screening level ecotoxicity values (See Section 3)

Determination of no risk or continuation of risk assessment

(2) Preliminary exposure assessment and risk calculation

Calculate potential exposure (intake) using all pathways, conservative assumptions

Compare maximum likely exposure levels to screening level benchmarks

Determination of no risk or continuation of risk assessment

(3) Problem formulation: assessment endpoint(s) selection and testable hypothesis

More comprehensive literature search for toxicity data

Identification of contaminants of potential ecological concern

including effects of mixtures of chemicals, multiple exposure pathways

Selection of assessment endpoints

Based on ecosystem/community/population of concern

Exposure characterization

More detailed description of site; contaminants present; extent and magnitude of contaminant concentrations, including spatial and temporal variability; environmental fate and transport; and potential bioavailability

Hazard characterization - ecotoxicologic effects

Formulate testable hypotheses

Agreement on selected assessment endpoints and testable hypotheses

(4) Problem formulation/Conceptual model development

Establishment of complete exposure pathways, including critical exposure pathways

Identification of ecotoxicological threats to specific trophic levels

Relationship between measurement and assessment endpoints

Link of exposure pathways to assessment and measurement endpoints

Establishment of study design and data needs

Result: completion of site work plan and sampling and analysis plan:

Assessment endpoints

Testable hypotheses

Site conceptual model

Measurement endpoints

Data needs

Study methodology and protocols

Study design, uncertainties, and assumptions

(uncertainties: bioavailability and toxicity in field; contaminant concentrations at exposure points)

Data quality objectives (should specify number, volume, and types of samples)

Data analysis procedures and

Data interpretation

(5) Site assessment to confirm ecological sampling and analysis plan

Verify that study design is appropriate and implementable

Final decision on reference area(s)

(6) Site field investigation

Field sampling and surveys

(7) Risk characterization

Data analyses results

Replace assumed parameter values with site-specific values

Integration of exposure and effects into assessment endpoints

Different types of data interpreted through weight-of-evidence approach

(8) Risk management

Steps 1 and 2 are a screening process; Steps 3 and 4 refine the problem and lead to development of a site work plan. Detailed discussions of each of these points is provided in the full document. In addition, some examples of contaminant effects and food chain pathways are given. Decisions among the risk manager, risk assessor, and other involved professionals follow steps 2 through 5 and 8 (Figure 2-2).

The U.S. EPA Office of Policy Analysis/Office of Policy Planning and Evaluation conducted a study on the nature and extent, assessment methods, and management issues relating to ecological damages and risks at Superfund and RCRA facilities (U.S. EPA, 1989d-g). Methods used at these sites include screening-level methods, methods for characterizing actual ecological impacts, and methods for characterizing potential ecological impacts. The frequency of use of each method and endpoints evaluated were discussed. Each major methodological approach is evaluated in terms of the ecological assumptions inherent in the approach, the types of ecological impacts it characterizes, its main limitations, and its utility for risk management. At 52 Superfund sites, three main approaches were used to characterize actual impacts: (1) evaluation of the biotic community structure, (2) analysis of the morphological and/or physiological condition of individual organisms, and (3) comparison of environmental concentrations of contaminants to ecological benchmark levels. Four methods were used to characterize potential impacts: (1) comparison of measured and/or projected environmental concentrations of contaminants to ecological benchmark levels (the quotient method), (2) evaluation of potential impacts from estimates of exposure potential, (3) evaluation of potential impacts from estimates of hazard potential based on toxicity tests, and (4) quantitative risk modeling.

The *Summary Report on Issues in Ecological Risk Assessment* (U.S. EPA, 1991a) summarizes a series of information meetings and discussions sponsored by the U.S. EPA's Risk Assessment Forum at which issues in ecological risk assessment were discussed. Attendees included EPA scientists and experts in ecology and ecological risk assessment; coordination meetings were held with EPA's Science Advisory Board and representatives from state and federal agencies. Key points addressed were: the scope and content of future ecological guidelines, the nature and diversity of ecological assessments, approaches to characterizing and quantifying uncertainty in ecological hazard and exposure assessments, and

Steps in the Ecological Risk Assessment Process and Corresponding Decision Points in the Superfund Process

- | | | |
|----|--|----------|
| 1. | Preliminary Problem Formulation and Ecological Effects Evaluation | |
| 2. | Preliminary Exposure Estimate and Risk Calculation | SMDP (a) |
| 3. | Problem Formulation: Assessment Endpoint Selection Testable Hypothesis | SMDP (b) |
| 4. | Conceptual Model Development: Conceptual Model Measurement Endpoint Selection and Study Design | SMDP (c) |
| 5. | Site Assessment to Confirm Ecological Sampling and Analysis Plan | SMDP (d) |
| 6. | Site Field Investigation | |
| 7. | Risk Characterization | |
| 8. | Risk Management | SMDP (e) |

SMDP = Scientific/Management Decision Point

- (a) **Early Regional decision in the Superfund Accelerated Cleanup Model (SACM) concerning priority of the site.**
- (b) **Initial agreement on scope of the assessment and work plan.**
- (c) **Signing approval of the work plan and sampling and analysis plan for the ecological risk assessment.**
- (d) **Approval of any changes to the work plan or sampling and analysis plan.**
- (e) **Signing the Record of Decision.**

Figure 2-2. Steps and Decision Points in the U.S. EPA Risk Assessment/Superfund Process
Source: U.S. EPA, 1994a

the potential use of population modeling for characterizing ecological risk. These issues are central to the development of ecological risk assessment guidelines. Consistent guidelines are needed to address both conventional stresses from toxic chemicals as well as stresses such as habitat loss and global climate change.

A report, *Ecological Risk Assessment Issue Papers* (U.S. EPA, 1994b), contains four papers on topics relevant to ecological risk assessment as described in the Framework report: conceptual model development, characterization of exposure, effects characterization, and risk integration methods; other papers focus on five cross-cutting issues: ecological significance, biological stressors, ecological recovery, uncertainty, and ascertaining public values in ecological risk assessment. The issue papers, which were authored by experts outside of EPA, provide additional detail and technical guidance. The issue papers were peer reviewed at a workshop, the proceedings of which were also published (U.S. EPA, 1994c). The workshop report includes recommendations for revising the draft issue papers, identification of cross-cutting issues and future research needs, and suggestions for possible structures for a future EPA ecological risk assessment guideline. The Framework, issue papers, case studies, and other reports are all steps in the process of development of an Agency-wide ecological risk assessment guideline.

The U.S. EPA Office of Pesticide Programs uses an ecotoxicological approach to assess risk to ecological resources: laboratory toxicity bioassays to determine hazard, exposure determination using either monitoring data or model predictions, and comparison of exposure to hazard using the quotient method (Bascietto et al., 1990). In the quotient method, the exposure value is directly compared with a toxicity endpoint such as an LC_{50} value. Four steps comprise a preliminary ecological risk assessment: (1) review and evaluate the hazard data to identify the nature of the hazards, (2) identify and evaluate the observed quantitative relationship between dose and response, (3) identify the conditions of exposure such as intensity, frequency, and duration, and (4) combine the information on dose-response effects with that on exposure to estimate the probability that nontarget populations will be adversely affected (by actual use of the pesticide). Ecological assessment criteria containing safety factors that form the regulatory framework for pesticides developed by EPA are listed in Table 2-1. Estimated environmental concentrations (EEC) refer to concentrations in the media of concern.

Table 2-1. U.S. EPA Ecotoxicological Assessment Criteria for Pesticides		
Presumption of minimum hazard	Presumption that hazard may be mitigated by restricted use	Presumption of unacceptable hazard
Acute toxicity		
Mammals: media: $EEC < 1/5 LC_{50}$ intake: $mg/kg/day < 1/5 LD_{50}$	$1/5 LC_{50} \leq EEC < 1/2 LC_{50}$ $1/5 LD_{50} \leq mg/kg/day < 1/2 LD_{50}$	$EEC \geq 1/2 LC_{50}$ $mg/kg/day \geq 1/2 LD_{50}$
Birds: $EEC < 1/5 LC_{50}$ $mg/kg/day < 1/5 LD_{50}$	$1/5 LC_{50} \leq EEC < LC_{50}$ $1/5 LD_{50} \leq mg/kg/day < 1/2 LD_{50}$	$EEC \geq LC_{50}$ $mg/kg/day \geq 1/2 LD_{50}$
Aquatic organisms: $EEC < 1/10 LC_{50}$	$1/10 LC_{50} \leq EEC < 1/2 LC_{50}$	$EEC \geq 1/2 LC_{50}$
Chronic toxicity		
$EEC < \text{chronic no effect level}$	Not applicable	$EEC \geq \text{effect level}$

EEC = Estimated environmental concentrations

Source: Bascietto et al., 1990; Kendall, 1994

2.2. OTHER FEDERAL AGENCIES

2.2.1. Department of Energy

The U.S. DOE has published a guidance document that incorporates ecological information into the U.S. EPA's (1988b) RI/FS process (*Incorporating Ecological Risk Assessment into Remedial Investigation/Feasibility Study Work Plans*; U.S. DOE, 1994). The guidance is for DOE staff and contractor personnel and is to be used for environmental remediation planning and decision making at CERCLA sites. Guidance is provided in a concise, step-wise manner. Appendices provide a generic ecological work plan and outlines for an ecological field sampling plan and quality assurance project plan.

The process is outlined in 16 modules as follows:

Project Planning

- Statutory and Regulatory Mandates
- Role of EPA and Other Regulators
- Preliminary Hazardous Substance Characterization

Scoping

- Existing Site Information
- Ecological Input for RI/FS Scoping
- Develop Site Ecological Conceptual Model

Initial Evaluation

- Site Physical Features
- Potential Contaminant Pathways in Ecosystem

Work Plan Rationale

- Data Needs for Ecological Risk Assessment
- Work Plan Approach

RI/FS Tasks

- Determination of Assessment and Measurement Endpoints
- Ecological Data Evaluation Needs
- Ecological Field Sampling Plan
- Ecological Input to Quality Assurance Project Plan

Alternatives Evaluation

- Ecological Input to Baseline Risk Assessment
- Ecological Data Analysis for Comparison of Remedial Action Alternatives

For cleanup of the U.S. DOE Oak Ridge site, U.S. EPA criteria and screening benchmarks for chemicals lacking U.S. EPA criteria are applied to specific ecosystem sites. These criteria and screening benchmarks are discussed in Section 3 below. The U.S. DOE is also in the process of completing an internal document which will be a policy framework for using ecological risk assessment at DOE facilities (Beckert, 1995).

2.2.2. Department of Defense

Human health considerations drive clean-up values of the Installation Restoration Program. However, this program is being expanded to include ecological risk assessments.

The U.S. Army has developed two sets of guidelines for ecological risk assessment. The first set is a methodology and survey approach for the Edgewood Research Development and Engineering Center, *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites, Volume 1* (Wentsel et al., 1994). This volume provides guidance for conducting ecological risk assessments that comply with Superfund requirements at Army NPL sites as well as sites listed under the Base Realignment and Closure Program. The assessment process is based on EPA's Framework document; included are discussions of exposure and effects methods based on ecological risk theory, background history of risk analysis, and risk characterization. The second set of guidelines, *Risk Assessment Guidance for the U.S. Army Corps of Engineers, HTRW Program, Volume 2: Environmental Evaluation*, provides support for engineers and project managers. Earlier, the U.S. Army initiated an ecological risk assessment at the Rocky Mountain Arsenal and, along with other federal agencies, has supported the development of models and methods during the risk assessment process at this site. The Rocky Mountain Arsenal is one of the case studies reviewed in EPA/630/R-92/005 (U.S. EPA, 1993a). The U.S. Army Environmental Hygiene Agency has conducted ecological assessments at some of its ammunition plants (U.S. DA, 1991). Chemicals of concern were measured in media; bioaccumulation and evidence of organ histopathology were evaluated in animals and related to body burdens.

The U.S. Air Force and Navy are in the process of developing guidance for ecological risk assessments (DeSesso and Price, 1990; Muschett, 1992)

2.2.3. Department of the Interior

Damages (monetary compensation) to the public for injury to natural resources resulting from discharge of oil or release of a hazardous substance are made under CERCLA or under the Clean Water Act (FR 51:27674). This Natural Resource Damage Assessment (NRDA) does not provide for response or remedial actions. Type A NRDA are standard, simplified damage assessments and Type B NRDA are used in individual cases; techniques for the assessment are contained in five Type B Technical Information Documents: *Injury to Fish and Wildlife*, *Application of Air Models to Natural Resource Injury Assessment*, *Guidance on Use of Habitat Evaluation Procedures and Suitability Index Models for CERCLA Applications*, *Approaches to the Assessment of Injury to Soil Arising from Discharges of Hazardous Substances and Oil*, and *Techniques to Measure Damages to Natural Resources*. As an

example of their contents, the first document provides testing and sampling methodologies reported in the technical literature that may be used to determine injury (U.S. DOI, 1987).

2.2.4. National Oceanic and Atmospheric Administration

The National Oceanic and Atmospheric Administration has developed a set of sediment screening benchmarks for estuarine and coastal sediments (see Section 3.3).

2.3. NATIONAL RESEARCH COUNCIL

In 1989, the National Research Council's Committee on Risk Assessment Methodology (CRAM) identified and evaluated issues in risk assessment that have occurred since publication of the 1983 document, *Risk Assessment in the Federal Government: Managing the Process*. One of the issues considered was the development of a conceptual framework for ecological risk assessment (NRC, 1993). CRAM identified ecological risk assessment as the characterization of the adverse effects, both biological and nonbiological, of environmental exposures to hazards, both unintentional hazards as well as management activities, imposed by human activities. The CRAM report was summarized and discussed by Barnthouse (1994) as follows.

Following consideration of six types of case studies [(1) assessing the effects of tributyltin on Chesapeake Bay shellfish populations, (2) testing agricultural chemicals for ecological effects, (3) predicting the fate and effects of polychlorinated biphenyls, (4) assessing responses of populations to habitat change, (5) regulating species introductions, and (6) harvesting the Georges Bank multispecies fishery], CRAM concluded that the underlying risk process for both human health and ecological risk assessment is the same. However, the NRC (1983) human health scheme needed modification to (1) address the legal and other regulatory considerations that influence the initial stages and focus of ecological risk assessments, and (2) develop effective communication between scientists and risk managers and the public. The most common obvious deficiency of the case studies was related to Risk Characterization. The CRAM report also discussed the scope of applicability of ecological risk assessment and identified major categories of scientific uncertainty for which additional research is needed.

The CRAM integrated human health/ecological risk assessment framework consists of four components: **hazard identification**, **exposure assessment**, **exposure-response assessment** and **risk characterization** (Figure 2-3). Discussions between the risk assessor and risk manager result in decisions about **risk management**. Hazard identification was redefined as the determination of need for further study or immediate management action in response to

the presence of a hazardous agent. Exposure assessment was defined as the determination of the extent of exposure to a hazardous agent before or after application of regulatory controls. Exposure-response assessment was defined as the determination of the relation between the magnitude of exposure and the probability of occurrence of the effects in question. Risk characterization was defined as the description of the nature and the magnitude of risk, including attendant uncertainty. In addition to the basic components, the implications of policy consideration on hazard identification and the need for follow-up monitoring studies, validation studies, and basic research are emphasized in the framework. The CRAM framework is not intended as an explicit methodology for ecological risk assessment.

The CRAM report further made five recommendations concerning the future development and use of ecological risk assessment:

Risk assessors, risk managers, and regulatory agencies should adopt a uniform framework for ecological risk assessment,

State and federal agencies should expand the issue of risk assessment in strategic planning and priority-setting as a means of focusing their resources on critical environmental problems and uncertainties,

Agencies should support the development of improved methods of risk characterization and consistent guidelines for applying them,

Agencies should institute follow-up research and monitoring studies to determine the accuracy of predictions and resolve uncertainties, and

Agencies should support systematic research programs to improve the credibility and utility of ecological risk assessment.

In comparing the CRAM integrated human health/ecological risk assessment framework to the U.S. EPA's 1992 Framework, the following differences can be noted: CRAM's hazard identification is replaced by EPA's problem formulation, CRAM's exposure assessment and exposure-response assessment are combined in a step identified as analysis by EPA which in turn is divided into characterization of exposure and characterization of ecological effects. The U.S. EPA framework is more specifically ecological than CRAM's, and the relationship between assessment and management reflects the U.S. EPA's regulatory mission.

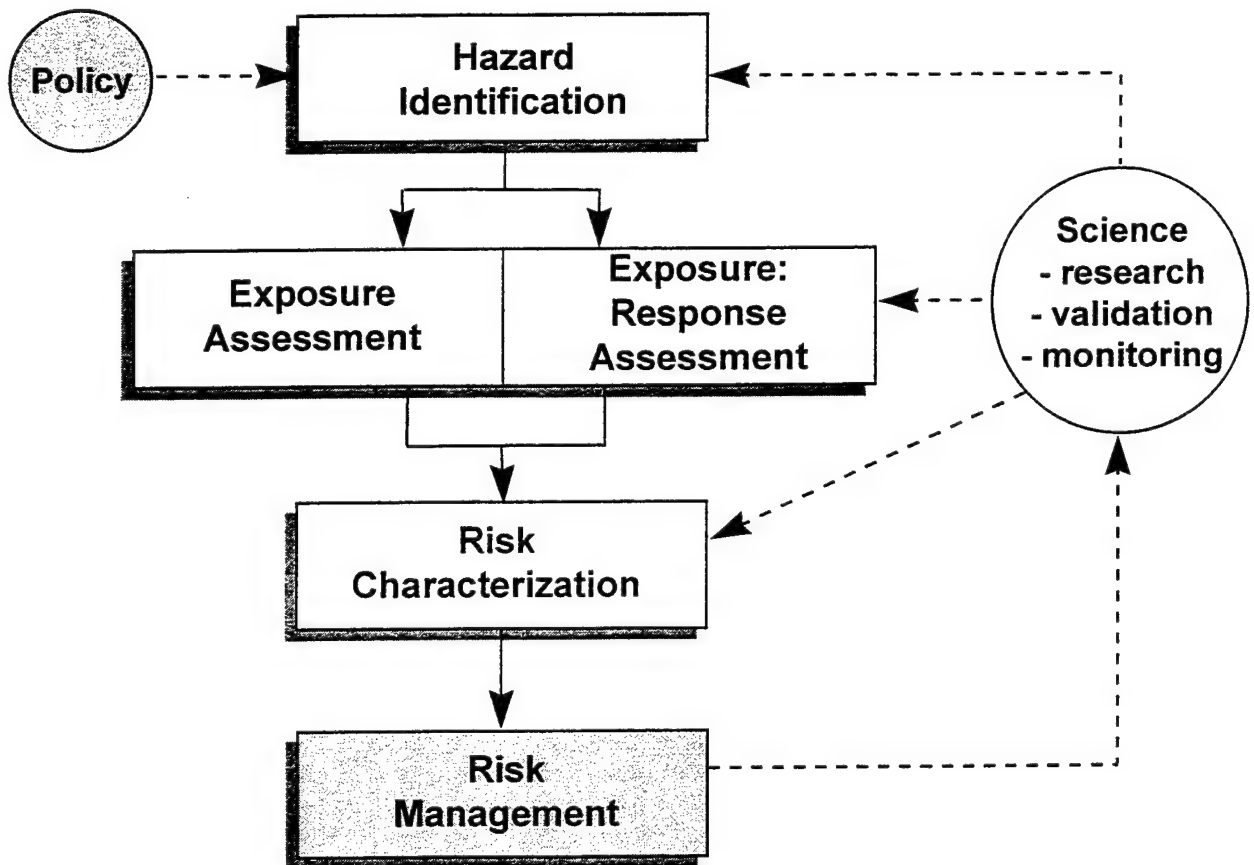


Figure 2-3. The CRAM Integrated Human Health/Ecological Risk Assessment Framework
Source: NRC, 1993

2.4. STATE AGENCIES

Several states have published guidance documents for ecological risk assessment. Only two are listed here. The State of California Environmental Protection Agency (1994) has published draft guidelines for the investigation, monitoring, and remediation of hazardous waste sites and facilities. These are similar to U.S. EPA guidelines.

The state of Washington has developed sediment criteria for marine waters (Ginn and Pastorok 1992). The approach to developing these criteria is discussed in the section on Sediment Criteria (Section 3.3).

2.5. OTHER GROUPS

The Water Environment Research Foundation has sponsored development of a *Methodology for Aquatic Ecological Risk Assessment* (Parkhurst et al., 1994). The methodology can be used at any site receiving chemical or waste effluents. They suggest a three-tier approach: Tier 1 is a conservative screening level approach based on comparing expected water concentrations of chemicals with acute and chronic risk criteria or by estimating concentrations of chemicals in fish from bioconcentration factors. During this process chemicals of potential concern are identified, exposure pathways are characterized, and receptors and the magnitude of risk associated with each chemical are identified. The entire process involves the steps of problem formulation, source characterization, exposure assessment, ecological receptor characterization, ecological effects characterization, risk characterization, and risk management.

During the Tier 1 process it is assumed that (1) the exposure scenario is worst case (the most sensitive species are exposed to the highest concentrations of chemicals), (2) chemicals are 100% bioavailable, (3) a healthy diverse, multi-trophic level aquatic community is present, and (4) U.S. EPA or other water quality criteria or screening benchmarks are conservative. Completion of Tier 1 results in the following: a list of chemicals of potential concern; calculations of quotients for individual and summed chemicals; and a description of the methodology, assumptions, and data.

Tier 2, also a screening assessment, is more detailed, complex, and rigorous than Tier 1, but also uses existing data. The chemicals of potential concern not screened out in Tier 1 undergo a quantitative risk assessment using lower uncertainties. Risks are based on probabilities; the percent of species or genera affected, and site-specific ecological receptors. Site-specific water quality criteria may be developed. Tier 3 uses the same basic methodology as Tier 2, but newly collected site-specific data are included in the assessment.

The Society of Environmental Toxicology and Chemistry (SETAC) supports a journal, sponsors workshops, conducts topical symposia, and publishes books to promote communication among the multiple groups involved in ecological risk assessment. A SETAC Ecological Risk Assessment Advisory Group has addressed several issues including environmental fate and assessment models and validation of ecorisk procedures (SETAC, 1994a).

Two recent books offer approaches and methods for ecological risk assessment. *Ecological Risk Assessment* (Suter, 1993) presents concepts that are important to risk assessment and discusses all components of the risk assessment paradigm. *Ecological Assessment of Hazardous Waste Sites* (Maughan, 1993) provides technical and regulatory information necessary to plan, prepare, and implement an ecological risk assessment of a hazardous waste site in compliance with current government regulations. The subject matter covers the overall approach to assessments as well as techniques for evaluating three aspects of ecological assessments: terrestrial pathways of contaminants, sediment quality and contamination, and toxicity testing.

3. CHEMICAL CRITERIA AND BENCHMARK SCREENING VALUES

In order to assess effects, toxicity tests and criteria must be available. Acute and chronic toxicity are the toxicological endpoints for development of regulations and assessment of adverse effects. Toxic concentrations of chemicals to organisms are media specific, but few criteria for chemicals in various media have thus far been developed. The U.S. EPA has developed criteria to protect aquatic organisms in water and sediments. Where data are available but are not sufficient for criteria development, several groups have developed screening benchmarks. These are described below.

3.1. AQUATIC ORGANISMS

Regulations for acceptable levels of chemicals in water have traditionally been based on laboratory studies using fish, invertebrates, or plants and the application of a safety or uncertainty factor. Data on toxic effects to aquatic organisms are available to federal, state, and local governments through the AQUIRE Data Base maintained at the U.S. EPA's Environmental Research Laboratory at Duluth. AQUIRE is part of ECOTOX, a U.S. EPA ecotoxicity data base of chemical-specific toxicity values for aquatic life, terrestrial plants, and wildlife which has been supported, in part, through SERDP. AQUIRE is not commercially available through U.S. EPA. Data are also available from the published literature, much of which has been included in AQUIRE.

3.1.1. National Ambient Water Quality Criteria (NAWQC)

CERCLA §121(d)(2)(A) states that remedial actions shall at least attain (federal) NAWQC established under the Clean Water Act [also known as the Federal Water Pollution Control Act, §303(c)(2)(B)]. These criteria for the protection of aquatic life are published by the U.S. EPA as a requirement of the Clean Water Act. In determining if NAWQC are relevant and appropriate, one must consider the "designated or potential use of the surface water, the environmental media affected, the purposes for which the criteria were developed, and the latest information available" [CERCLA §121(d)(2)(B)].

In 1980, the U.S. EPA published the first ambient WQC for 64 chemicals (45 FR 79318, Nov. 28, 1980). Since that time, the guidelines for calculating NAWQC have been updated (50 FR 30784, July 29, 1985) and additional criteria have been published (U.S. EPA, 1991b). Unfortunately, data on whole classes of chemicals such as some pesticides and munitions compounds are lacking. Criteria have been developed for both freshwater and saltwater organisms and for both acute and chronic exposures. Criteria were developed for protection of most aquatic species most of the time with a reasonable degree of confidence. NAWQC were not designed for contaminant screening; however, because they may be Applicable or Relevant and Appropriate Requirements (ARARs) for Superfund site clean-ups, any chemical that exceeds its NAWQC must be considered a contaminant of concern.

Acute criteria (also referred to as Criterion Maximum Concentrations) are developed from standard aquatic toxicity tests of 48-hour (invertebrates) or 96-hour (fish) duration (Stephan et al., 1985). Juvenile or adult organisms from eight representative freshwater or saltwater families are tested; the test endpoints are median lethal concentrations for death (LC_{50}) or some equivalent median effect concentration (EC_{50}). Acute criteria are usually calculated as the fifth percentile of the distribution of 48- to 96-hour LC_{50} values, or equivalent effect for each chemical (defined as the final acute value [FAV]), divided by two; however, depending on the available data and data results, other methods of determining the FAV may be used (See Stephan et al., 1985 for details). Acute criteria are intended to correspond to the highest concentration of a chemical that would cause less than 50% mortality in 5% or less of the tested genera in a brief (1-hour) exposure. That is, acute values are one-hour average concentrations not to be exceeded more than once every 3 years. Data for some chemicals are related to water quality characteristics such as pH or hardness.

Chronic criteria (also referred to as Criterion Continuous Concentrations) are developed from standard aquatic toxicity tests that include most or all of the life cycle of the test organism; the test endpoints include observations of lethality, growth, reproductive success, and deformities. They are derived from life cycle tests with three representative families (a fish, an invertebrate, and a sensitive species) and include at least eight LC_{50} values and three

chronic values (CV), the latter defined as the geometric mean of the lowest-observed-effect-concentration and the no-observed-effect-concentration. CVs are the FAVs divided by the final acute/chronic ratio (FACR) which is the geometric mean of quotients of at least three LC_{50}/CV ratios from tests of different families of aquatic organisms. Depending on data availability, quality, and lowest values, alternate values (Final Plant Value or the Final Residue Value) may be used as the chronic criteria (See Stephan et al., 1985 for details). The NAWQC chronic values are four-day average concentrations not to be exceeded more than once every 3 years.

Site-specific water quality criteria may be derived from NAWQC (U.S. EPA, 1984). The site-specific guidelines provide a series of protocols for modifying NAWQC to reflect local environmental conditions. These guidelines take into consideration site-specific variations in species composition, physical factors, and chemical water quality variables. Site-specific criteria may be the same as, higher than, or lower than national criteria. In some cases, states have developed water quality values; if these are lower than NAWQC, the state values would take precedence over the federal values.

Acute and chronic ambient WQC for 16 chemicals present in the Great Lakes System have been proposed (58 FR 20802, April 16, 1993). The portions of the 1985 National Guidelines that pertain to freshwater organisms serve as the basis for the methodology for the Great Lakes criteria. Thus, the criteria are based primarily on laboratory toxicity data for a variety of aquatic species (fish, benthic invertebrates, and plants) which are representative of the species in the environment as a whole. Because they are based on newer data, some of the criteria differ from NAWQC.

3.1.2. Other Methodologies

Before the development of WQC guidelines, aquatic criteria were based on application factors (APHA, 1975; NAS, 1973; U.S. EPA, 1976). One approach involves multiplying the lowest lethal concentration or EC_{50} value by a conservative application factor. The application factor for conversion to chronic effects was based on the nature of the chemical: for nonpersistent or noncumulative effects, the 24-hour average concentration was not to exceed 0.05 of the LC_{50} of the most sensitive species tested; for persistent or cumulative chemicals the 24-hour average concentration was not to exceed 0.01 of the LC_{50} value of the most sensitive species tested.

The U.S. EPA Office of Pollution Prevention and Toxics in their Cleaner Technologies Substitutes Assessment effort has established a methodology for ranking of chemicals according to their potential to be toxic to aquatic organisms (U.S. EPA, 1994d). Concentrations of chemicals that may result in a significant risk to aquatic organisms, called

Ecotoxicity Concern Concentrations (ECO CC) are calculated by dividing acute or chronic toxicity values for fish, invertebrates, or algae by an Assessment Factor (AsF). The AsF is determined by the availability of the data: (1) if the available data contain only one or two acute toxicity values, the acute value is divided by 1000; (2) if the data contain three acute values (no chronic value) the lowest acute value is divided by 100; (3) if the data contain one chronic value, the chronic value for the most sensitive species is divided by 10; (4) if the data contain three chronic values, the lowest chronic value is divided by 10; and (5) if the data contain a measured chronic value from a field study, the measured chronic value is divided by 1. Chronic toxicity values take precedent over acute values. The values are ranked and used to guide the selection of alternate chemicals that are less hazardous to aquatic organisms.

3.1.3. Screening Benchmarks

A suite of values (contained in a data base) was developed for DOE's Environmental Restoration Program at sites such as Oak Ridge National Laboratory (ORNL). The screening benchmarks, which identify a certain level of significant effects from laboratory or field data for a particular species or group of organisms, are compared to concentrations in ambient media. Because screening benchmarks should provide a high degree of confidence that a chemical is not hazardous, greater conservatism than that given by the NAWQC was deemed necessary. Therefore, alternative screening benchmarks, based on different conceptual approaches to estimate concentrations causing significant effects were developed.

For chemicals for which NAWQC are not available, the following screening benchmarks are proposed for freshwater organisms. A more detailed discussion of each screening benchmark and the methods by which the benchmarks were derived is given in ORNL (1994) and Suter and Mabrey (1994). It should be noted that in order to make the benchmarks acceptable among federal agencies, peer review or evaluation of the study chosen to represent the screening benchmark should be undertaken. U.S. EPA Region 8 has approved these screening benchmarks for use at the Rocky Flats site.

Tier 2 secondary acute and chronic values. Tier 2 values were developed based on the method described in EPA's Proposed Water Quality Guidance for the Great Lakes System (58 FR 20802, April 16, 1993). This method allows for the derivation of benchmarks (equivalent to final acute values and final chronic values) with fewer data points than that required for NAWQC. Tier 2 values presented in this data base are concentrations that would be expected to be higher than the NAWQC in no more than 20% of the cases. Secondary Chronic Values (SCV) are regulatory standards or equivalents, and any chemical concentration that exceeds them is clearly of potential concern.

National ambient water quality Final Chronic Value. For chlordane, the NAWQC derived by EPA is based on the Final Residue Value; however, in order to have a benchmark for effects on aquatic organisms rather than piscivorous wildlife (which have a separate set of benchmarks), the Final Chronic Value for chlordane derived by EPA is also included in the data file.

Lowest chronic value - fish. This value is the lowest concentration reported in the literature to be a threshold for statistically significant chronic toxicity in fish, and it is used by the EPA as equivalent to a chronic NAWQC when data are insufficient for deriving a NAWQC or a final chronic value.

Estimated lowest chronic value - fish. This value was estimated by ORNL staff by extrapolation from 96-hr LC_{50} values for fish when no measured chronic values were available for fish.

Lowest chronic value - daphnids. This value is the lowest concentration reported in the literature to be the threshold for statistically significant chronic toxicity to daphnids. It has been used by the EPA as equivalent to a chronic NAWQC when data are insufficient to derive a NAWQC, Tier 2 SCV, or a final chronic value.

Estimated lowest chronic value - daphnids. This value was estimated by ORNL staff by extrapolation from 48-hr LC_{50} values for daphnids when no measured chronic values were available.

Lowest chronic value - nondaphnid invertebrates. This value is the lowest concentration reported in the literature to be the threshold for statistically significant chronic toxicity to aquatic invertebrates other than daphnids.

Lowest chronic value - aquatic plants. This value is the lowest concentration reported in the literature to be the threshold for biologically important toxicity to aquatic plants, in a test of at least 96-hr duration.

Lowest test EC_{20} - fish. This test endpoint, developed by ORNL, is the highest tested concentration of a chemical that caused less than a 20% reduction in (1) weight of young fish per initial female fish in a partial or full life cycle test or (2) the weight of young per egg in an early life-stage test.

Estimated lowest test EC_{20} - fish. This value was extrapolated from 96-h LC_{50} data by ORNL staff.

Lowest test EC₂₀ - daphnids. This test endpoint, developed by ORNL staff, is the highest tested concentration of a chemical that caused less than a 20% reduction in the product of growth, fecundity, and survivorship in a chronic test with a daphnid species.

Sensitive species test EC₂₀. This screening benchmark was developed by ORNL staff, and is calculated in the same way as the chronic National Ambient Water Quality Criteria (i.e., the fifth percentile of the species sensitivity distribution) except that the test EC₂₀ values are used in place of chronic values.

Population EC₂₀. This value, developed as a screening benchmark by ORNL staff, is an estimate of the continuous (chronic) concentration that would cause a 20% reduction in the recruit abundance of largemouth bass.

Suter and Mabrey (1994) recommend that ambient chemical concentrations be compared to all of the above listed benchmarks. If the NAWQC or SCV are not exceeded but other benchmarks are, contaminants of concern should be selected on the basis of the number of benchmarks exceeded and the conservatism of the particular benchmark values exceeded.

Screening benchmarks are also being developed for radioactivity. For exposure of aquatic organisms to radiation, a dose rate of 0.4 mGy/h has been recommended by the U.S. DOE (Blaylock et al., 1993). DOE's recommended dose rate is based on a summary of published studies in the National Council on Radiation Protection and Measurements (NCRP, 1991). In that report the developing eggs and young of some species of teleost fish were identified as the most radiosensitive organisms. DOE recommends that if an exposure assessment indicates that a dose rate of 0.1 mGy/h is exceeded, then a more detailed evaluation of the potential consequences to endemic populations should be undertaken.

In the absence of measured toxicity data, structure-activity relationships (SARs) can be used to estimate toxicity. Clements (1988) presented 49 structure-activity relationships currently used by the U.S. EPA, Office of Pollution Prevention and Toxics, to estimate the toxicity of industrial organics to aquatic organisms. The SARs can be applied to three categories of organic chemicals: (1) neutral organics which are nonreactive and nonionizable, (2) neutral organics which are reactive and show excess toxicity in addition to narcosis, and (3) surface active organic compounds such as surfactants, and polycationic polymers. The SARs may be used for predicting acute toxicity to fish and aquatic invertebrates and chronic toxicity to fish, invertebrates, and algae. Structure-activity regressions, based on chemical classifications, are presented in Clements (1988), Clements et al. (1993), and Hermans et al. (1984). Background on the use of structure-activity relationships based on presumed toxic mode of action classifications can be found in Bradbury (1994), Russom et al. (1991), and Verhaar et al. (1992).

3.2. TERRESTRIAL WILDLIFE

Data on the toxicity of chemicals to terrestrial wildlife can be obtained from the U.S. EPA's ECOTOX data base, U.S. Fish and Wildlife Service reports, EPA assessment and criteria documents, and Public Health Service toxicity profiles. ECOTOX contains a wildlife toxicity data base, TERRE-TOX that was developed by the U.S. EPA Environmental Research Laboratory in Corvallis (Meyers and Schiller, 1986). Other data bases with toxicity studies include IRIS (Integrated Risk Information System), HSDB (Hazardous Substances Database), HEAST (Health Effects Assessment Summary Tables), and BIOSIS (Biosciences Information Services). Although much of the data are for laboratory animals, extrapolations to wildlife species can be made. The U.S. Fish and Wildlife Service has data compilations on toxic concentrations of chemicals, including pesticides, to birds. The U.S. EPA Office of Pesticide Programs has published a guidance document for conducting terrestrial field studies (U.S. EPA, 1988c). These tests are discussed in Section 4.3.

The U.S. EPA's *Wildlife Exposure Factors Handbook* (U.S. EPA, 1993b) provides data on 15 species of birds, 11 species of mammals, and 8 species of amphibians and reptiles that can be used for exposure assessment and to support the quantification of risk estimates. Included are normalizing factors for body weight, growth rate and metabolic rate; contact rate factors for the oral, inhalation and dermal route of intake; population dynamics; and seasonal activities. Also included are allometric equations that can be used to estimate exposure factors when data are lacking, and common equations used to estimate exposure.

3.2.1. Proposed Water Quality Criteria

A methodology for the derivation of chronic WQC for bioaccumulative chemicals and associated criteria for DDT, mercury, PCBs, and TCDD have been proposed for piscivorous wildlife (mink, river otter, eagle, osprey, and belted kingfisher) in the Great Lakes System (58 FR 20802, April 16, 1993). The "wildlife criteria are the highest calculated aqueous concentrations of substances which cause no significant reduction in growth, reproduction, viability or usefulness of a population of exposed animals that use Great Lakes System waters for food or drinking over several generations." The Great Lakes Water Quality Guidance also contains a procedure for determining bioaccumulation factors which are used to estimate the intake of chemicals via consumption of fish by wildlife species.

3.2.2. Screening Benchmarks

There are no terrestrial criteria similar to NAWQC for assessment of effects of chemicals to terrestrial wildlife. In the absence of toxicity data for species of wildlife, the general methodologies used by EPA in the Great Lakes Water Quality Guidance and for

deriving human toxicity values from laboratory animal data can be used to derive screening benchmarks for wildlife species (ORNL, 1994; Opresko et al., 1995). This is the method used by the U.S. EPA for Reference Doses (RfDs) and unit risks for carcinogenicity (U.S. EPA, 1986a, 1986b). In extrapolating dose values from one animal species to another, differences in metabolic rates are reflected in body surface area or body weight raised to the 3/4 power (U.S. EPA, 1995b). Opresko et al. (1995) provide benchmarks for terrestrial mammals and birds for 55 chemicals.

The ORNL data file (Opresko et al., 1995) contains screening benchmarks for chemical contaminants which may be of concern at DOE's Oak Ridge site. The benchmarks presented in this file are values believed to be nonhazardous for the following wildlife species: eight species of mammals (short-tailed shrew, little brown bat, white-footed mouse, meadow vole, cottontail rabbit, mink, red fox, and whitetail deer) and nine species of birds (American robin, American woodcock, wild turkey, belted kingfisher, great blue heron, barred owl, barn owl, Cooper's hawk, and red-tailed hawk). The selected species are representative of the fauna occurring at the Oak Ridge site; however, the assumption is that the benchmarks would be applicable to similar species of similar body size at other sites. Exceedence of the benchmarks does not indicate any particular level or type of risk, but does indicate cause for further study. Concentrations below the benchmarks are not expected to result in significant effects, particularly in those cases where the supporting data are based on multigeneration reproductive toxicity studies. As in the case of aquatic screening benchmarks, it should be noted that in order to make the benchmarks acceptable among federal agencies, peer review or evaluation of the study chosen to represent the screening benchmark should be undertaken.

The methodology is as follows. **NOAELs** (no-observed-adverse-effect levels) and/or **LOAELs** (lowest-observed-adverse-effect levels) were identified from studies conducted primarily on laboratory rodents. The equivalent NOAEL for a particular species of wildlife ($NOAEL_w$) was obtained by scaling the laboratory data ($NOAEL_t$) on the basis of differences in body size according to the following equation:

$$NOAEL_w = NOAEL_t \left(\frac{bw_t}{bw_w} \right)^{1/4} \quad (1)$$

In cases where only a LOAEL was available, the NOAEL was estimated as being equivalent to 1/10th of the LOAEL. If the only available data consisted of a NOAEL (or a LOAEL) for a subchronic exposure (approximately 3 months to 1 yr), then the equivalent NOAEL or LOAEL for a chronic exposure was estimated as being 1/10th of the value for the subchronic exposure.

The **dietary level**, or concentration in food (C_f , in mg/kg food) which would result in a dose equivalent to the NOAEL (assuming no other exposure through other environmental media) was calculated from the food factor f , which is the amount of food consumed per unit body weight per day:

$$C_f = \frac{NOAEL_w}{f} \quad (2)$$

Food factors for species of wildlife were derived from the rate of food consumption (F , in g/day or kg/day) and the body weight (bw , in g or kg):

$$f = \frac{F}{bw} \quad (3)$$

In the absence of empirical data, rates of food consumption (F , in kg/day) for laboratory mammals can be estimated from allometric regression models based on body weight (in kg) (U.S. EPA, 1988d):

$$F = 0.056(bw)^{0.6611} \quad (\text{laboratory mammals}) \quad (4)$$

$$F = 0.054(bw)^{0.9451} \quad (\text{moist diet}) \quad (5)$$

$$F = 0.049(bw)^{0.6087} \quad (\text{dry diet}) \quad (6)$$

In the absence of specific information on the body weights of the test animals, EPA uses default values (U.S. EPA, 1986c). F was estimated using Equation 4 and the EPA's default body weights (0.35 kg for rats and 0.03 kg for mice). Reference body weights for particular strains of laboratory animals, and for specific age groups corresponding to subchronic or chronic exposures are available (U.S. EPA, 1988d) and these can also be used in the equations. Default values for food consumption and food factors for common laboratory species (rats, mice, dogs, rabbits, etc.) have also been used by U.S. EPA (1986c, 1988d) for estimating equivalent dose levels for laboratory studies in which the exposure was reported only as a dietary concentration. Generally, the rates of food consumption for laboratory species as derived from Equations 4 are higher than the EPA default values.

Food consumption rates are available for some species of wildlife (U.S. EPA, 1993b). In the absence of experimental data, F values (g/day) can be estimated from allometric regression models based on metabolic rate and expressed in terms of body weight (g) (Nagy, 1987):

$$F = 0.235(bw)^{0.822} \text{ (placental mammals)} \quad (7)$$

$$F = 0.621(bw)^{0.564} \text{ (rodents)} \quad (8)$$

$$F = 0.577(bw)^{0.727} \text{ (herbivores)} \quad (9)$$

$$F = 0.492(bw)^{0.673} \text{ (marsupials)} \quad (10)$$

$$F = 0.648(bw)^{0.651} \text{ (birds)} \quad (11)$$

$$F = 0.398(bw)^{0.850} \text{ (passerine birds)} \quad (12)$$

The concentration of the contaminant in the drinking water of an animal (C_w , in mg/L) resulting in a dose equivalent to a $NOAEL_w$ can be calculated from the daily water consumption rate (W , in L/day) and the average body weight (bw_w) for the species:

$$C_w = \frac{NOAEL_w \times bw_w}{W} \quad (13)$$

If known, the water factor ω (the rate of water consumption per unit body weight [W/bw]) can be used in a manner identical to that for the food factor.

$$C_w = \frac{NOAEL_w}{\omega} \quad (14)$$

If empirical data are not available, W (in L/day) can be estimated from allometric regression models based on body weight (in kg) (U.S. EPA, 1988d):

$$W = 0.10(bw)^{0.7377} \text{ (laboratory mammals)} \quad (15)$$

$$W = 0.009(bw)^{1.2044} \text{ (mammals, moist diet)} \quad (16)$$

$$W = 0.093(bw)^{0.7584} \text{ (mammals, dry diet)} \quad (17)$$

In the absence of specific information on the body weights of the test animals, EPA uses default values (see U.S. EPA, 1986c). W was estimated using Equation 15 and the

default body weights. Reference body weights for particular strains of laboratory animals, and for specific age groups corresponding to subchronic or chronic exposures are available (U.S. EPA, 1988d) and these can also be used in the equations. Default values for water consumption and w for common laboratory species have been used by U.S. EPA (1986c, 1988d) for estimating equivalent dose levels for laboratory studies in which the exposure was given only as a concentration in the animals' drinking water. Generally, the rates of water consumption for laboratory species as derived from Equations 15 are higher than the EPA default values.

Water consumption rates are available for some species of mammalian wildlife (see U.S. EPA, 1993b). Water consumption rates (in L/day) can also be estimated from allometric regression models based on body weight (in kg) (Calder and Braun, 1983):

$$W = 0.099(bw)^{0.90} \quad (18)$$

A similar model has also been developed for birds (Calder and Braun, 1983):

$$W = 0.059(bw)^{0.67} \quad (19)$$

The State of California Environmental Protection Agency (1994) suggests that in the selection of terrestrial species or receptors, an example group of default representative species to represent functional groups for various ecoregions should be developed. These species should include a primary producer, a primary consumer, and higher level consumers; a decomposer may also be included.

3.3. BENTHIC ORGANISMS

3.3.1. Approaches to Development of Sediment Quality Criteria

Sediment quality criteria (SQC) for the protection of benthic organisms have been proposed for only a few chemicals. There are various approaches to developing SQC; these different approaches provide different levels of assessment and can be used in combination or in a tiered assessment approach. Some of the methods depend on chemical properties and thus can be applied to only a certain chemical or class of chemicals. Sources, advantages, and limitations/uncertainties in these methods were reviewed by Chapman (1989) and Adams et al. (1992) except where otherwise noted. The methods are:

Comparison of chemical concentrations in contaminated sediments with concentrations
in reference sediments

Comparison of interstitial (pore) water concentrations with U.S. EPA NAWQC

Interstitial water toxicity tests
Sediment/water equilibrium partitioning approach (EqP) (nonionic organic compounds)
Field sediment bioassays
Spiked sediment bioassays
Screening level concentration (SLC) approach
Apparent effects threshold (AET) approach
Sediment quality triad approach (combination of bulk sediment chemistry, sediment bioassays, and in situ bioeffects)
Tissue residue approach
Acid volatile sulfides (AVS) (metals)
Benthic macroinvertebrate community structure and function

Reference (background) sediment concentration. This approach is based on the comparison of chemical concentrations in contaminated sediments with concentrations in reference sediments. The comparison of concentrations in contaminated sediments with concentrations in reference sediments will provide information on chemicals of concern. Appropriate reference sediments must be obtained or established for comparisons. At present, the ASTM is developing guidelines for selection of sediment background sampling locations (ASTM Subcommittee E47.13.01).

Advantages of this approach are its simplicity, requiring only contaminated sediment concentrations; in addition, there is no need for toxicity testing. Disadvantages include (1) the current lack of reference concentrations, (2) application to only inorganics as theoretically there are no background data on synthetic organic chemicals, (3) data are site-specific, (4) no consideration of the bioavailability of chemicals, and (5) the lack of biological effects data.

Interstitial water quality criteria. This approach compares contaminant concentrations in interstitial water with U.S. EPA NAWQC. This approach assumes that the interstitial water is in equilibrium with the surrounding sediment and that any toxicity is due to the soluble or uncomplexed fractions of chemicals in the sediment. This approach assumes that the sensitivities of benthic organisms are the same as those of organisms found in the water column and that sediment ingestion is not a route of contaminant exposure. Disadvantages are that standardized methods for extracting sediment water do not exist, extraction may alter the toxicity of the water, water quality criteria for contaminants such as PAHs that partition to sediments are not available, chemical interactions cannot be predicted, and the approach does not use toxicological data from the sediment of interest.

Interstitial water toxicity. Aquatic organisms are exposed to water extracted from sediments in the laboratory. As for the interstitial water quality criteria approach above, this approach assumes that the interstitial water is in equilibrium with the surrounding sediment

and that any toxicity is due to the soluble or uncomplexed fractions of chemicals in the sediment. Limitations/disadvantages for this approach are the same as for the interstitial water quality criteria approach. In addition availability of interstitial water may limit the duration of toxicity tests. However, samples in which organisms are affected can be chemically analyzed.

Equilibrium partitioning (EqP) approach. This approach incorporates the U.S. EPA Water Quality Criteria together with a normalization to organic carbon to correct for differences in bioavailability among sediments. As with the interstitial water quality approach, this approach assumes that the partitioning of the chemical between sediment organic carbon, pore water, and the organisms is at equilibrium and that any toxicity is due to the bioavailable soluble or uncomplexed fractions of chemicals in the pore water.

Using this approach, SQC are calculated from a water quality criterion as follows: $SQC = K_p \times WQC$ where K_p (the partition coefficient) is the ratio of the sediment concentration of a chemical to the interstitial water concentration in units of L/kg and the WQC are in units of $\mu\text{g/L}$; K_p is also calculated by $f_{oc} \times K_{oc}$ where f_{oc} is the mass fraction of organic carbon in the sediment and K_{oc} is the partition coefficient for sediment organic carbon. The K_{oc} , if unavailable, may be estimated from regression equations that relate K_{oc} to the octanol-water partition coefficient, K_{ow} for the chemical. Thus the $SQC = f_{oc} \times K_{oc} \times WQC$ (Di Toro et al., 1991; U.S. EPA, 1993c).

SQC could serve as thresholds for identifying the sediment as contaminated. There are limited field validation data for this method. Because of the uncertainty of the application of the theory to various field settings, as well as site-specific differences in potential applications, the U.S. EPA (1992d) Science Advisory Board recommends ranges of values that denote where adverse biological effects are likely to occur, unlikely to occur, or unknown and further evaluation is required. They also recommended development of a series of chronic sediment toxicity tests; additional field verification of laboratory predictions; further research on bioavailability, sediment chemistry, and bioaccumulation; and additional guidance on application of the criteria. The U.S. EPA (1992d) lists the following sources of uncertainty associated with application to the natural environment: "(1) the extent to which factors other than organic carbon, which may influence bioavailability for nonionic organic chemicals, may vary in the environment, (2) not all sediments are in equilibrium (good K_{ow} values are hard to obtain), (3) occasionally K_{ow} may not be a good predictor of K_{oc} , (5) partitioning of contaminants to and from sediments may be kinetic-limited, and (6) short-term bioassays may underestimate effects observed in long-term or full life cycle exposures to contaminants. The variability of toxic effects among different sediments can be reduced: if chemical concentrations are normalized on an organic carbon basis or toxicity is based on pore water

concentrations, then biological effects occur within a factor of two or three for different sediments (Di Toro et al., 1991).

Screening level concentration (SLC) approach. Field data on the concentrations of specific nonpolar organic contaminants in sediments and the presence of specific taxa of benthic fauna in that sediment are used to calculate the SLC (Neff et al., 1988). The SLC is an estimate of the highest concentration, normalized to sediment organic carbon concentration, of a particular nonpolar organic contaminant in sediments that can be tolerated by approximately 95% of benthic infauna. Exceedence of the concentration could lead to environmental degradation and therefore would warrant further investigation. Neff et al. (1988) calculated SLC values for five contaminants in freshwater sediments and nine contaminants in saltwater sediments. Large data bases on contaminant concentrations in sediments, carbon concentration in the sediment, and species composition of benthic infauna are required for calculation of SLC.

Apparent effects threshold (AET). The AET is the concentration of a single chemical or chemical class in sediments above which a particular biological effect has always been observed and thus is predicted to be observed in other areas with similar concentrations of that chemical (Ginn and Pastorok, 1992). As reviewed in Chapman (1989) and Adams et al. (1992), field-collected data are used to identify concentrations of chemicals above which statistically significant biological effects are always expected relative to appropriate reference sediments. A wide variety of organisms (ideally site-specific) and biological tests can be used to obtain the effects data. The process involves (1) collection of matched chemical (analytical measurements) and biological effects (benthic infaunal measurements, bulk sediment bioassays) data from field sediment samples, (2) identification of statistically significant different impacted and nonimpacted sediments sites, and (3) determination of AET for each chemical of interest using the paired data sets for all sediment sites in a given area. AET are based on dry-weight normalization rather than organic carbon normalization concentrations. The AET approach may be both over and under protective of the environment. This approach has been used to derive AET values for 64 organic and inorganic chemicals in Puget Sound, Washington. Following public comment, the state of Washington in 1991 adopted Sediment Management Standards which are, in part, based on the AET approach.

Acid volatile sulfides (AVS). Published data indicate that total metals in sediments are not good estimators of the bioavailable fraction of the metals present. Sulfide, as a precipitant of heavy metals, is important in controlling the bioavailability of metals in anoxic sediments. During the extraction of AVS by an acidification process, metals are liberated from the sediment. Concentrations of these simultaneously extracted metals (SEM) can be determined. A molar ratio of SEM for bivalent metals to AVS of greater than one indicates bioavailability and potential toxicity (Di Toro et al., 1990; Allen et al., 1991).

Because bioavailability of chemical contaminants is site (sediment) specific, many investigators suggest a three-tiered approach for an ecological risk assessment of contaminated sediments: toxicity testing, a survey of the benthic macroinvertebrate community, and comparison of concentrations of chemicals suspected to be causing toxicity with benchmark values (see below) (Burton and Scott, 1992).

3.3.2. Proposed Sediment Quality Criteria

Based on the above approaches, criteria and various screening levels have been suggested and utilized. Under the authority of Section 304(a) of the Clean Water Act, the U.S. EPA has proposed SQC for the protection of benthic organisms (and the food chain leading up to humans) for five priority pollutant nonionic organic chemicals: fluoranthene, acenaphthene, phenanthrene, dieldrin, and endrin (U.S. EPA, 1993d-h). These criteria were calculated based on the Equilibrium Partitioning Approach (EqP). They are expressed in micrograms of chemical per gram organic carbon and apply to sediments with $\geq 0.2\%$ organic carbon. At this time, separate criteria have been developed for saltwater and freshwater sediments. The U.S. EPA Science Advisory Board provided technical review of the methodology and supporting science (U.S. EPA, 1992d).

The specific regulatory uses of SQC as defined in CERCLA have not been established; they are not Applicable or Relevant and Appropriate Requirements. Rather, they set baselines and trigger points for federal and state decisions to prevent further contamination and to clean up some contaminated areas. The U.S. EPA is identifying and evaluating a range of possible uses to which final SQC may be applied. These include a basis for water quality assessment reports under CWA 305(b), a basis for total maximum daily loads under section 303(d), and water quality based effluent limits in NPDES permits or as a possible standard for clean-up strategies under CWA and other statutes. The criteria are not to be used alone; EPA is currently developing implementation and technical guidance that would be used with these criteria.

3.3.3. Screening Benchmarks

Using the U.S. EPA methodology of EqP (U.S. EPA, 1993c), Hull and Suter (1994) calculated sediment quality benchmarks for 42 additional nonionic organic chemicals. They used K_{ow} provided by U.S. EPA (1992e; 1994e), calculated K_{oc} , and the previously discussed water quality benchmarks developed at ORNL (Section 3.1).

Sediment screening benchmarks have been proposed by other agencies. The following approaches to development of sediment quality screening benchmarks and their basis for development have been reviewed in ORNL (1994) and Hull and Suter (1994). These authors

recommend the EqP approach for screening nonpolar organic contaminants, the National Oceanic and Atmospheric Administration approach for inorganic chemicals, and pore water analysis for polar organic compounds (to be compared to water quality benchmarks). Supplemental benchmarks are provided from the province of Ontario, Canada, the states of Washington and Wisconsin, and the U.S. EPA Region V. These approaches are described in the following paragraphs.

National Oceanic and Atmospheric Administration. Data from estuarine and coastal sediment samples collected throughout the United States annually were used to evaluate three approaches to the establishment of effects-based criteria: the Equilibrium Partitioning (EqP) approach, the spiked sediment toxicity test approach, and various methods of evaluating synoptically collected biological and chemical data in field surveys. Biological effects observed or predicted by these methods were ranked and effects ranges (Effects Range-Low [ER-L] and Effects Range-Median [ER-M]) were identified (Long and Morgan, 1991; Long et al., 1993 as reviewed in Hull and Suter, 1994). The ER-M is an upper benchmark. Identified are chemical concentrations above which adverse effects may be first expected and the concentration above which adverse effects are expected in most cases. Although the values are for estuarine and coastal sediments, they may be applied to freshwater systems. NOAA benchmarks are available for inorganic chemicals (Long et al., 1993). This method has been recommended as a sediment screening benchmark by the U.S. EPA Region IV.

Ontario Ministry of the Environment. The Ontario Ministry of the Environment used the SLC approach to develop sediment quality guidelines for the province of Ontario. They developed two effect-level guidelines for inorganic chemicals. The low effect level indicates a level of sediment contamination that can be tolerated by most benthic organisms; it is the 5th percentile using the SLC method. The severe effect level indicates the level at which pronounced disturbance of the sediment-dwelling community can be expected; it is calculated as the 95th percentile using the SLC method. This sediment concentration would be detrimental to most benthic organisms. The values are based on sediments in Ontario and benthic organisms found within the province (Persaud et al., 1990).

Beak Consultants of Canada also developed potential sediment guidelines for inorganic chemicals for the Ontario Ministry of the Environment. These are lower benchmarks (than those in the above paragraph) that use several approaches: background concentrations (most metals), SLC, assuming 4% total organic carbon (arsenic and nickel), and toxicity tests (chromium and copper) (Hart et al., 1988).

Wisconsin Department of Natural Resources. Geisy and Hoke (1990) derived criteria for inorganic chemicals using the background approach. The values were based on dredge material suitability for in-water disposal.

EPA Region V. Sediment classification guidelines for inorganic chemicals are taken from Geisy and Hoke (1990). Ranges of values are given for sediments that are considered nonpolluted, moderately polluted, or heavily polluted. The values are applied to sediments of the Great Lakes Harbors. The values are applicable for determining the suitability of dredged material for open water disposal. However, only the mercury guideline is strictly adhered to.

Washington State. Sediment quality standards for 47 chemicals or groups of chemicals have been developed for sediments associated with marine waters for the Washington State Department of Ecology (Ginn and Pastorok 1992). The chemicals include 8 metals, 32 nonpolar organic compounds, and 7 ionizable organic compounds. With the exception of phenanthrene, whose standard is based on the EqP approach, the standards are based on a biological effects approach that uses the lowest AET values of four biological indicators: amphipod (*Rhepoxynius abronius*) mortality, bivalve (*Crassostrea gigas*) larval abnormality, Microtox[®] (*Photobacterium phosphoreum*) bacterial luminescence bioassay, and abundances of major taxa of indigenous benthic infauna. Sediment standards were also established for three sediment management activities: source control standards, cleanup screening levels, and minimum cleanup levels. Direct biological testing such as sediment bioassays, and assessment of indigenous macroinvertebrate communities may be used to confirm or override the sediment standards.

3.4. TERRESTRIAL PLANTS

There are currently no promulgated benchmark values for terrestrial plants. Data for the calculation of potential screening benchmarks are available from the open literature, several bibliographical sources, and from the U.S. EPA's ECOTOX Data Base, which contains the PHYTOTOX Data Base that was developed at the Environmental Research Laboratory - Corvallis. As part of the ECOTOX effort, work is proceeding on updating PHYTOTOX and improving user accessibility. One data base on screening benchmarks for terrestrial plants was located and is described below.

A standard method for deriving screening benchmarks for phytotoxicity (assessing contaminants in soil or soil solution with respect to their toxicity to plants) has been derived by Will and Suter (1995a; ORNL, 1994). Benchmarks have been derived for 38 chemicals associated with U.S. DOE sites. In most cases, the toxicity values are based on a 20% reduction in growth or yield (considered a LOEC), of primarily domestic cultivars. Other response parameters as well as growth media (solution, soil, or other), exposure duration, and other effects concentrations are noted.

The general method that was used in estimating these screening benchmarks is based on the National Oceanographic and Atmospheric Administration's (NOAA) method for deriving the Effects Range Low (ER-L) which has been recommended as a sediment screening benchmark by EPA Region IV. The ER-L is the tenth percentile of the distribution of the various toxic effects thresholds for various organisms in sediments.

In the case of plants, the toxic effect endpoint was the lowest observed effect concentration (LOEC), defined here as the lowest applied concentration of the chemical that gave a greater than 20% reduction in a measured response. In some cases, the LOEC for the test was the lowest concentration tested (LCT) or the only concentration tested. Twenty percent reduction in plant growth or yield was used as the threshold for significant effects to be consistent with other screening benchmarks for ecological risk assessment and with current regulatory practice.

The benchmarks for terrestrial plants were derived by rank ordering the LOEC values and then picking a number that approximated the tenth percentile. Statistical fitting was not used because there was seldom sufficient data and because these benchmarks are to be used as screening values and do not require the consistency and precision of regulatory criteria. If there were 10 or fewer values for a chemical, the lowest LOEC was used. If there were more than 10 values, the tenth percentile LOEC value was used. If the tenth percentile fell between LOEC values, a value was chosen by interpolation. In all cases, benchmark values were rounded to one significant figure.

According to Will and Suter (1995a), another possible source of benchmark values is values recommended in published reviews of the phytotoxicity literature. When primary literature is unavailable for a particular contaminant, concentrations identified in reviews as thresholds for phytotoxicity are used as benchmarks. In addition, when fewer than three LOEC values were found for a chemical, and a toxicity threshold from a review was lower than the lowest LOEC, the toxicity threshold was used as the benchmark for that chemical.

The benchmarks reported here were divided into two categories based on the type of rooting medium used in the toxicity tests - soil or solution. Tests conducted in natural soils are assumed to be representative of the exposure of plants to contaminants measured in field soils. Soil benchmarks are based on data provided only by toxicity studies in either the field or pots. In these tests, total concentrations of chemicals are reported. Correspondingly, most of the soil concentrations of metals reported from waste sites are from extractions with hydrochloric acid (HCl) or other mineral acids which are intended to provide total concentrations. Similarly, concentrations of organic contaminants in waste site soils are total concentrations derived from rigorous solvent extractions. However, in some cases, toxicity tests report concentrations extracted from contaminated soils, but various extractants are

used that may not yield total concentrations. More commonly, the concentrations reported are nominal concentrations of a soluble form (i.e., a highly bioavailable form) of the chemical added to soil. Thus, in applying benchmarks which are based on total concentrations in the test soils, the extraction methods for waste site concentrations should be considered.

Tests conducted in nutrient solutions are assumed to be representative of exposures of plants to contaminants measured in soil solutions (e.g., from lysimeter samples or possibly from aqueous extracts of soil) or in very shallow groundwater (e.g., plants in the vicinity of seeps and springs). Solution benchmarks include data from toxicity tests conducted using whole plants rooted in aqueous nutrient solutions. Tests are commonly conducted in this manner because plants are assumed to be exposed to contaminants in the solution phase of soil and the presence of soil in test systems reduces the experimenter's degree of control over exposure. Groundwater samples from waste sites are typically acidified before analysis to obtain total concentrations, but some samples are filtered before acidification.

The authors note that the site-specific nature of soil characteristics and plant species must be considered in any evaluation of chemicals at a site. Plant toxicity may be affected by many variables: pH, Eh, cation exchange capacity, moisture content, interactions with other elements, and organic matter and clay content of the soil. In addition, different species react to different contaminants with varying degrees of toxicity, and the sensitivity of plants may be affected by their physiological condition. No systematic tests that thoroughly examine the effects of these variables on plant toxicity are known to these authors. An assessor must realize that these soil characteristics play a large part in plant toxicity and incorporate these site-specific considerations in the evaluation of the potential hazards of a chemical. If chemical concentrations reported in field soils that support vigorous and diverse plant communities exceed one or more of the benchmarks presented in this report or if a benchmark exceeds background soil concentrations, it is generally safe to assume that the benchmark is a poor measure of risk at that site. Thus, these benchmarks are to serve for contaminant screening only.

3.5. SOIL INVERTEBRATES

Will and Suter (1995b) present a standard method for deriving benchmark concentrations of contaminants with respect to their toxicity to soil and litter invertebrates including earthworms, other invertebrates, and heterotrophic bacteria and fungi. Twenty percent reduction in growth, reproduction, or activity was used as the threshold for significant effects. The general method that was used in estimating these screening benchmarks is based on the NOAA method for deriving the Effects Range Low (ER-L) which has been recommended as a sediment screening benchmark by EPA Region IV. The ER-L is the tenth

percentile of the distribution of the various toxic effects thresholds for various organisms in sediments. Benchmarks were derived for earthworms and microbial heterotrophs. Data were insufficient for derivation of soil benchmarks for other soil-dwelling invertebrates.

4. TOXICITY TESTS FOR USE IN RISK ASSESSMENT

Chemical toxicity test data are an important component of risk assessments. As noted throughout the report, where sufficient data are available, criteria have been developed. Because criteria are available for relatively few chemicals, toxicity-based tests using single chemicals or mixtures of chemicals under laboratory conditions or using field-collected samples which may involve complex mixtures can be used to screen for toxicity. Toxicity tests can be acute (short-term) or chronic (long-term, including several life stages). Toxicity tests with field samples tested in situ or in the laboratory measure the aggregate toxicity of all chemicals present and are a realistic measure of the bioavailability of the chemicals. These tests are for use at the organism (species) level of organization; they are generally not applicable to communities. Various standard test methods have been developed to provide toxicologic benchmarks. EPA methods manuals and ASTM guidelines and procedures are available for conducting toxicity tests with various media and species, both in the laboratory and in the field; these methods and procedures are too numerous to discuss in detail here. It should be noted that when using laboratory tests, the species tested should be representative of the species found at a site. More data are available for aquatic toxicity tests than for tests with other media.

4.1 AQUATIC TOXICITY TESTS

Standard flow-through, static-renewal, and static methods are available for measuring the acute toxicity of effluents to fish and invertebrates (Peltier and Weber, 1985; ASTM, 1988; 1991). Short-term tests for fish, invertebrates, and algae as well as preparation of elutriates from solid samples have also been published (Greene et al., 1988). The ASTM (1988) has developed standard toxicity tests for four species of bivalves. Chronic toxicity tests for invertebrates and fish typically last 21 days and several months, respectively. Relatively short-term (7 day) tests to estimate long-term effects have also been developed (APHA, 1989; Peltier and Weber, 1985; Horning and Weber, 1985; Weber et al., 1988). Endpoints include lethality, reproductive potential, and growth.

4.2 TESTS FOR SEDIMENT TOXICITY

The Society of Environmental Toxicology and Chemistry - Europe held a workshop and published a guidance document on sediment toxicity tests and bioassays (SETAC, 1994b). The workshop was concerned with the methodology and data interpretation of bioassays (laboratory toxicity tests utilizing sediments collected in the field) and toxicity tests (laboratory tests utilizing clean natural or artificial sediment that has been spiked with a chemical) from both freshwater and marine sites. Guidance is given for procedures starting with collection of samples and overlying water, through design and conduction of the test, to statistical analysis and interpretation of the results. The document summarizes the best available methodology.

The ASTM has published a guide of procedures for obtaining, storing, characterizing, and manipulating saltwater and freshwater sediments for use in laboratory sediment toxicity evaluations (E1391-90, ASTM, 1993). ASTM has published guidelines for conducting sediment toxicity tests with freshwater invertebrates (E1383-90, ASTM, 1993). Test procedures are described for amphipods, *Hyaella azteca*; midges, *Chironomus tetans* and *C. riparius*; zooplankton, *Daphnia* sp. and *Ceriodaphnia*; and the burrowing mayfly, *Hexagenia limbata*. Methodologies are provided for both field-collected and laboratory spiked sediments. It should be noted that in comparison to chemical analyses, toxicity tests reflect the bioavailability of sediment-associated contaminants. Also, in using field-collected sediments, the mixtures of chemicals found in the environment can be tested.

4.3. SOIL CONTAMINATION

Toxicity tests for animals, plants and microbes exposed to contaminated soils are reviewed in *Ecological Techniques for the Assessment of Terrestrial Superfund Sites* (U.S. EPA, 1992f). In addition to summation of the test methods, intended uses, previous applications/regulatory precedence, requirements for development and implementation, and potential problems and limitations are discussed. Animal and plant test methods using bulk soil collected at hazardous waste sites or conducted in the field using various species are described in the appendices. For screening level assessments, tests using seed germination, root elongation, and worm mortality are often applied.

5. CASE STUDIES

Guidance in conducting ecological risk assessments can be gleaned from published documents and the many and diverse risk assessments already performed at Superfund sites.

Some of these studies are available from the published literature; others have been summarized by the U.S. EPA.

The Office of Policy Analysis/Office of Policy, Planning, and Evaluation conducted a study of the nature, extent, assessment methods, and management issues relating to ecological damages and risks at Superfund sites (U.S. EPA, 1989d; 1989g). These studies preceded publication of the Framework document discussed in Section 2.1. Three categories of methods are described: (1) screening level approaches for determining the overall nature and extent of ecological impacts associated with Superfund sites and establishing remedial priorities at hazardous waste sites, (2) methods for characterizing actual ecological impacts resulting from the release of chemicals at specific sites, and (3) methods for characterizing potential ecological impacts that might result from the release of chemicals at specific sites. Methods used in regulatory and policy studies to characterize the ecological impacts associated with Office of Solid Waste and Emergency Response sites are also evaluated. Screening level approaches include evaluating impacts at sites for prioritization of sites and applying the Hazard Ranking System (HRS), a scoring system that evaluates factors such as toxicity of substances and the number and type of potential receptors that are indicators of risk to humans and the environment.

Actual impacts differ from potential impacts in that actual impacts are based on sampling results at sites whereas potential impacts are predictive, based on chemical hazard, exposure potential and exposure-response relationships. Three main approaches were used to characterize actual impacts at Superfund sites: (1) evaluation of biotic community structure, (2) evaluation of individual morphology or physiology, and (3) comparison of contaminant concentrations to ecological benchmarks. In the first approach, quantitative sampling, qualitative surveys, and aerial photography were used to address endpoints such as diversity indices, indicator species, description of the community and the absence of or stressed vegetation. In the second approach, field sampling, histopathology, necropsy, records of mortality, and detailed field studies were used to address the endpoints of tissue residue levels, disease/abnormalities, and reproduction. In these two approaches, comparisons were made with reference sites. In the third approach, field sampling was used to characterize contaminated media and calculate hazard quotients. This approach was used most commonly for aquatic or wetland ecosystems; no specific organisms or endpoints were identified.

In the qualitative survey of the biotic community, only sites with major impacts can be identified. In addition, areal extent of the impacts can be observed. Quantitative measures provided identification of small, subtle impacts to individuals or populations. In addition, the severity of impacts and the areal extent of impacts were provided. In the second approach, direct evidence of injury to individual organisms and the areal extent or magnitude of impacts

is provided. The third approach does not provide evidence of actual impacts, but the nature and extent of contamination above benchmarks as well as identification of exposure pathways are provided.

Four main methods were used to characterize potential impacts at 56 Office of Solid Waste and Emergency Response sites (listed in decreasing order of use): (1) comparison of measured or projected environmental concentrations of contaminants to ecological benchmark levels (i.e., the quotient method), (2) evaluation of potential impacts from estimates of exposure potential, (3) evaluation of potential impacts from estimates of hazard potential (based on media toxicity test results), and quantitative modeling to predict the likelihood of adverse effects to the ecosystem. The techniques and measurement endpoints are discussed. Method 1 was used most frequently for aquatic ecosystems whereas exposure potential was used at terrestrial sites.

Scientists from the U.S. EPA analyzed a cross-section of ecological assessment case studies (U.S. EPA, 1993a). The twelve case studies were wide-ranging in scope, representing a variety of ecosystems, ecological endpoints, chemical and nonchemical stressors, and programmatic requirements within EPA. Although the assessments were conducted before publication of the *Framework for Ecological Risk Assessment*, they were evaluated at peer review workshops as to whether they effectively addressed the general components of an ecological risk assessment. It was concluded that the studies were generally consistent with the Framework's principles. Specific problems in defining and conducting each stage of the risk assessments - problem formulation, analysis and risk characterization - were described. Themes that emerged from the case studies were: the need for discussions between the risk assessor, risk manager, and relevant experts at the beginning and end of the assessment; the need for clear problem formulation; while models were useful, sensitivity analyses and validation studies were often insufficient to evaluate the relevance to the real world situations; field studies provided a level of realism not attainable in laboratory studies (however, finding a reference site for comparison purposes was difficult); presentation of results varied greatly. A second set of case studies has recently been reviewed and published by the U.S. EPA (1994f).

Case studies have also been published in other U.S. EPA documents, books (Maughan, 1993), and in recent issues of journals including, *Environmental Toxicology and Chemistry* (November, 1992, December, 1994).

6. RISK CHARACTERIZATION METHODS

6.1. HAZARD QUOTIENT (HQ)

The simplest and most common quantitative approach to risk estimates is the quotient method. The method compares toxicological-effect concentrations with predicted or measured exposure concentrations of a toxic substance. Exposure levels may be estimated environmental concentrations (EEC) or estimated contaminant intake in mg/kg/day (dose); these are compared to a known effect such as the LC_{50} or predicted threshold for effects, referred to as a NOAEL value. If the ratio of the two equals or exceeds 1, a risk is inferred; if the ratio is less than 1, there is less likelihood of risk.

$$HQ = \frac{\text{Dose}}{\text{NOAEL}} \quad \text{or} \quad HQ = \frac{\text{EEC}}{\text{NOAEL}}$$

Risks for human intake of noncarcinogenic chemicals are evaluated by comparing the intake estimates from exposure assessment to the Reference Dose (RfD) of a chemical which is often based on laboratory studies using mammalian species (U.S. EPA, 1988e). Since RfDs are often based on laboratory animal studies, a body weight scaling factor or uncertainty factor(s) can be used to calculate equivalent doses for site-specific terrestrial vertebrates.

6.2. HAZARD INDEX (HI)

Hazard quotients for individual chemicals may be added to yield a hazard index. A hazard index of less than one indicates that exposure to all contaminants in a mixture falls within a safe level; a hazard index greater than one is a potential cause for concern. Contaminants with the same ecological effects endpoint should be summed. It should be noted that this approach assumes strict additivity among chemicals and does not incorporate potential synergistic or antagonistic interactions.

6.3. HAZARD RANKING SYSTEM (HRS)

HRS is a screening-level device for establishing remedial priorities at hazardous waste sites. Although based primarily on human health considerations, calculations of environmental threats are included (See 53 FR 51962, Dec. 23, 1988; 55 FR 51532, December 14, 1990). The HRS is used as a basis for placing sites on the NPL.

7. MODELS

The use of population modeling is an issue in ecological risk assessment (U.S. EPA, 1991a). Because it is not practical to conduct field studies that determine the effects of chemicals on entire populations, existing data can be used to project and infer effects on demographic properties (birth, growth, survival, and reproduction) at the population level. Matrix models, perturbation and sensitivity analyses, fisheries stock-recruitment models, empirical time-series models, and spatial models were discussed. Although of limited use for "applications such as projecting species-specific impacts in field situations, modeling techniques can provide an ecological framework for interpreting toxicity data and testing hypotheses, a technical basis for decision making, and a mechanism for examining alternative management strategies." According to Cairns and Niederlehner (1994), models can be used to extrapolate from toxicity test data to space and time scales that are ecologically relevant. Such extrapolation is accompanied by a considerable amount of uncertainty.

Models for use in transport and fate of chemicals, exposure assessments, and effects or predictive risk assessment are discussed in various chapters of Suter (1993). How models should be used, the degree of testing required, the uncertainty of ecosystem endpoints to be used, and the need for more data and also more relevant data are pointed out. The author concludes that "no single model will likely provide accurate estimates across a wide range of relevant spatial and temporal scales associated with different hazards, endpoints, and mandates for risk estimation and regulation."

A recent book edited by Kendall and Lacher (1994), *Wildlife Toxicology and Population Modeling: Integrated Studies of Agroecosystems* contains 50 conference papers on the use of models to assess effects of contaminants at the population level. Although the effects of pesticides on bird populations as measured by field studies were addressed, the purpose of the conference, in general, was to integrate the fields of population ecology and wildlife toxicology through approaches to modeling. The conference attendees recognized that no single model could be constructed to serve all purposes related to environmental risk assessment of avian exposure to pesticides. Therefore, specific models must be constructed to address specific needs. Aspects of avian toxicology amenable to modeling include:

- Fate and transport of pesticides,
- Exposure involving different species, chemicals, and routes,
- Uptake/metabolism/elimination models that show bioaccumulation, detoxification,
- Toxic effects (dose-response relationships),
- Extrapolation from one species to another,
- Thresholds of concern (mortality, reproduction, and sublethal effects)

Assessment of field trials for consequences of direct and indirect effects on local reduction and recovery,
Prediction of effects of local usage to refine management tools,
Long-term/regional patterns detected by exploratory models of monitoring data,
Effects of total product utilization using models that integrate impact of single applications with area and frequency of proposed use,
Community effects

Many of these aspects are applicable to other species and chemicals.

A Society of Environmental Toxicology and Chemistry Working Group is exploring the design and development of an operating ecological risk assessment modeling system (SETAC, 1995). The goal is to make models within subdisciplines of ecological risk assessment compatible for coupling within a system and to consider rules for standardizing compatibility of models developed in the future.

8. ISSUES IN ECOLOGICAL RISK ASSESSMENT

Issues in ecological risk assessment range from development of data points for ecological effects of specific contaminants to development of a uniform, agency-wide framework for ecological risk assessment. See Section 2.1 for a discussion of issue papers published by the U.S. EPA. The following list should not be considered exhaustive.

Development of additional Water Quality Criteria and criteria for other media/organisms. Some form of criteria and/or screening benchmarks for individual contaminants is desirable, either as cleanup levels or as screening techniques.

Development of screening benchmarks. In the absence of data to develop regulatory criteria for many chemicals found at hazardous waste sites, media-specific screening benchmarks need to be developed.

Characterization of ecosystems at risk. Generic ecological risk assessment methodologies may be tailored to the ecosystem at risk. These include terrestrial, terrestrial/aquatic, freshwater, estuarine, marine, and wetland (U.S. EPA, 1989d). Subcategories (e.g. freshwater lakes and streams) and additional characterizations may be found in the literature. Although not a measurable endpoint by itself, ecosystem integrity should be a primary goal of ecological risk assessment (Cairns and McCormick, 1992).

Endpoint selection. In order to undertake an environmental risk assessment, the environmental value(s) to be protected must be clearly defined. These values or endpoints are of two types, assessment and measurement endpoints (Suter, 1989). Both assessment endpoints (ecological values to be protected) and measurement endpoints (parameters to be measured) need to be defined at the beginning of an assessment. Measurement endpoints may be used as surrogates for assessment endpoints. Because it is often impractical to measure changes in assessment endpoints such as forest production over a large geographic area or a fish population in a reservoir, measurement endpoints such as growth reduction in plants or fish LC_{50} values may be measured in the field or laboratory and used as indicators of hazard. Assessment endpoints should have social relevance, biological relevance, an unambiguous operational definition, be measurable or predictable, susceptibility to the hazard, and logically related to the decision (Suter, 1989). Potential assessment endpoints include population extinction, abundance, yield/production, age/size class structure, mortality; community market/sport value, recreational quality, change to less useful desired type; ecosystem productivity. Good measurement endpoints correspond to or are predictive of an assessment endpoint, are readily measured, appropriate to the scale of the site, are appropriate to the exposure pathway, are appropriate temporal dynamics have low natural variability, are diagnostic, broadly applicable, standard, existing data series. Potential measurement endpoints are listed below. These concepts are further discussed in Suter (1989; 1990), Suter and Barnthouse (1993), and U.S. EPA (1991a). Examples of assessment endpoints, indicators of effects, and measurement endpoints for chemicals applied to the environment are described in Suter and Barnthouse (1993).

The U.S. EPA (1991a; 1992c) suggests that specific criteria should be developed to select a suite of ecological endpoints germane to a particular environmental problem and for a particular ecological system. They plan to develop a suite of generic endpoints with subsets of endpoints appropriate to specific problems. However, it must be kept in mind that the inherent natural variability of the environment makes it difficult to compare populations and communities among sites. Potential measurement endpoints for use in ecological risk assessments have been suggested by many agencies and authors including U.S. EPA (1989c), Suter (1989; 1990), and Suter and Barnthouse (1993).

Organism or individual level

Mortality

Sublethal endpoints

Changes in growth

Changes in behavior

Changes in endurance

Changes in susceptibility to disease, predation

Histopathological effects

Gross abnormalities
Physiological/biochemical/blood disorders
Reproductive impairment (fecundity)
Tissue residues

Population level

Species abundance
Reproductive potential
Occurrence and distribution (extinction)
Abundance comparison with reference site/baseline
Gross morbidity, mortality
Age/size/class structure

Community level

Species composition, richness, diversity, evenness
Local extinction
Biomass
Interspecies relationships
Community type

Ecosystem level

Biomass
Productivity
Nutrient dynamics

Data quality objectives. DQOs should be defined prior to data collection at a site and should address regulatory requirements as well as decisions to be made (including levels of uncertainty) with the collected data.

Indicator species. The species to study at a site may be chosen on the basis of "importance," using one or more of the following factors:

- (1) the species is commercially or recreationally valuable,
- (2) the species is designated endangered or threatened,
- (3) the species affects the well-being of a species satisfying conditions (1) or (2),
- (4) the species is sufficiently sensitive to serve as an indicator of environmental stresses before significant effects on other species occur.

Critical habitats/Endangered species. Some habitats such as wetlands are more vulnerable to stressors than others. A list of habitats identified by the HRS and that may require special consideration is given in U.S. EPA (1994a).

Biomarkers. Chemical or physiological responses or tissue residues measured in individual organisms do not necessarily indicate effects at higher levels of organization, i.e., population, community, and ecosystem. Biomarkers are predominately measures of exposure and, to some degree, bioavailability of contaminants. Biomarkers are often non-chemical specific indicators of stress. Biomarkers are discussed in many of the above cited documents including U.S. EPA (1989b) and McCarthy and Shugart (1990).

Field surveys. Community analysis can be used as a screening tool; however, because of natural variability and subtle habitat differences, field surveys alone cannot be used to indicate effects of hazardous substances on populations or communities at a site. Field surveys coupled with chemical analyses and toxicity tests could suggest cause-effect relationships.

Selection of appropriate reference sites. Because of natural variability and subtle habitat differences, appropriate reference sites are difficult to find. There is also the question of how many reference sites should be used in the comparison.

Models. Appropriate models for use in the absence of data and for specific endpoints need to be identified and validated. See Section 7.

Stress-response and recovery relationships. Ecosystem (as well as population and community) resilience or recovery from a perturbation depends on several factors including the magnitude, rate, and frequency of disturbance; ecosystem characteristics; and the presence of refugia (U.S. EPA, 1991a). Current methods and models are inadequate for predicting subtle changes or incremental trends in ecosystems. Environmental impacts can be better assessed with the incorporation of ecosystem functional endpoints and ecosystem resilience into the assessment process (Cairns and Niederlehner, 1993).

Uncertainties. The issue of uncertainties in ecological risk assessments is important and commonly discussed as there are uncertainties in each of the components of an ecological risk assessment. The U.S. EPA (1991a) and other sources identify the following limitations and uncertainties in the hazard and risk assessment processes:

- Model selection/model parameters
- Errors in parameter measurements
- Chemical transport/fate/transformation
- Route(s) of exposure/organism behavior
- Exposure concentrations/spatial variations
- Temporal variation in magnitude and duration of exposure
- Exposure indicators
- Use of biomarkers - relation to higher level effects

Endpoint sensitivity - choice/use of chronic endpoints
Interactions/effects of multiple stressor exposures
Extrapolation among toxicological endpoints - acute to chronic
Taxonomic extrapolations - interspecies sensitivity
Life-stage sensitivity
Laboratory-to-field extrapolations
Dose scaling and allometry
Ecosystem resilience

The CRAM (NRC, 1993) report identifies four major areas in which scientific consensus is lacking. These are:

Extrapolation across scales of time, space, and ecological organization,
Quantification of uncertainty,
Validation of predictive tools, and
Economic valuation of ecological resources

Issues cited in other reports include those involving toxicity assessment:

Chemical quantitative structure-activity relationships
Interspecies extrapolation
Acute to chronic extrapolation
Extrapolation of laboratory results to predict in situ toxicity. Laboratory tests are usually more conservative estimates of in situ toxicity because they do not take into consideration bioavailability and chemical degradation.
Comparative sensitivity of laboratory and field test species
Sensitive life stages - Sensitivity to test chemicals varies greatly among life stages of an organism. Although young life stages are generally more sensitive than adults, some stages such as the eggs of fish are more resistant than fry or larvae. There are also size differences in sensitivity.
Use of single species tests to predict effects on communities, ecosystems..

Risk communication. Most of the guideline documents mentioned in this report emphasized the need for greater communication among non-technical personnel (project managers/coordinators), ecologists/biologists, and the public.

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